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1	IN THE UNITED STATES DISTRICT COURT
2	NORTHERN DISTRICT OF OHIO
3	EASTERN DIVISION
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6	IN RE: NATIONAL PRESCRIPTION MDL No. 2804
	OPIATE LITIGATION
7	Case No. 17-md-2804
8	Judge Dan Aaron
	This Document Relates To: Polster
9	
10	The County of Lake, Ohio v.
	Purdue Pharma L.P., et al.
11	Case No. 18-op-45032
12	
	The County of Trumbull, Ohio v.
13	Purdue Pharma L.P., et al.,
	Case No. 18-op-45079
14	
15	Track 3 Cases
16	
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17	
18	Remote videotaped deposition of
	WILLIAM DIFRANGIA
19	
20	
21	January 14, 2021
	9:03 a.m.
22	
23	
24	Renee L. Pellegrino, RPR, CLR
25	(Appearing Remotely)

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                 THE VIDEOGRAPHER: We are now on
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    the video record. Today is January 14th, 2021.
3
    The time is approximately 9:03 a.m. eastern
    standard time. We are here in the matter of
4
5
    the National Prescription Opiate Litigation,
    Track 3, to take the deposition of William
6
7
    DiFrangia.
                 Will counsel please identify
8
    themselves for the video record?
9
10
                 MR. BARNES: I'll start. On behalf
11
    of Giant Eagle, Robert Barnes. I'll be taking
12
    the deposition.
13
                 Other Defendants? CVS, can you
    identify yourself?
14
15
                 MR. MOYLAN: Daniel Moylan,
16
    Zuckerman Spaeder, for CVS.
17
                 MS. SWIFT: Kate Swift for
18
    Walgreens.
19
                 MR. BEISELL: Patrick Beisell, on
20
    behalf of Walmart.
21
                 MS. CONROY: Mildred Conroy, on
22
    behalf of the Plaintiffs.
23
                 THE VIDEOGRAPHER: If there are no
24
    other counsel, the court reporter may proceed.
25
                 THE COURT REPORTER: Due to the
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Page 10 1 need for this deposition to take place 2 remotely, will the parties stipulate that the 3 court reporter may swear in the witness over virtual video conference? 4 5 MR. BARNES: Yes. 6 MR. WEINBERGER: Yes. 7 MR. APPEL: Very briefly, this is Henry Appel. I am representing the Board of 8 9 Pharmacy and the witness in this case. I just 10 didn't verbalize quick enough. 11 WILLIAM DiFRANGIA, of lawful age, called 12 for examination, as provided by the Federal Rules 13 of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as 14 follows: 15 16 EXAMINATION OF WILLIAM DIFRANGIA 17 BY MR. BARNES: 18 Okay. Good morning, Mr. DiFrangia. Q. 19 Good morning. Α. 20 My name is Robert Barnes. I Q. 21 represent Giant Eagle. Giant Eagle is in a 22 group of Defendants which I'll call the pharmacy 23 Defendants. They include Giant Eagle, CVS, 24 Walgreens, Rite-Aid and Walmart. And from time 25 to time here in the deposition when I refer to

Page 11 "the pharmacy Defendants," I'll be referring to 1 that group of five Defendants. 2. 3 Is that okay with you? 4 Α. Yes. 5 Okay. Just a matter of Ο. housekeeping. Your counsel has asked us to take 6 7 a break at 11:30 to take care of some personal matters, so we'll break for lunch at 11:30 so he 8 can do that and we'll simultaneously have our 10 lunch. We'll break for an hour from 11:30 to 11 12:30. 12 Mr. DiFrangia, I sent to you via 13 overnight mail a couple of exhibit binders, 14 volume 1 and volume 2. Did you receive those? 15 Α. Yes. 16 Just for everybody's understanding, 0. 17 these exhibit binders were previously used in the depositions of Trey Edwards and George 18 19 Pavlich, who are also Ohio Board current or 20 former agents and inspectors. I will maintain 21 the designation of the exhibits. So, for 22 example, if I ask you to please look at Edwards Deposition Exhibit 3, it will be in the first 23 24 binder. The first binder contains the first 17 25 exhibits from Mr. Edwards' deposition and the

Page 12 second binder contains further Trey Edwards 1 2. deposition exhibits, plus some Pavlich exhibits, 3 and then at the very end, the last 11, are exhibits that we've solely designated in your 4 5 So we have Edwards plus Pavlich plus DiFrangia exhibits and all of your exhibits are 6 7 at the end of the second binder. Mr. DiFrangia, could you state your 8 9 full name for us? 10 Α. William DiFrangia. 11 And what's your date of birth? Ο. 12 May 23rd, 1982. Α. 13 Ο. And what is your current city of 14 residence, without giving me your specific address? 15 16 Boardman Township. Α. 17 Ohio? Q. 18 Α. Yes. 19 Now, you were -- you understand you Q. 20 were noticed to be deposed in this case pursuant 21 to deposition notice and subpoena. Have you 2.2 seen that? Α. 23 The subpoena I don't think I have 24 seen. I've obviously been notified that --2.5 Okay. If you look at the second Q.

Page 13 exhibit binder at the back, the Exhibits 1 1 2. through 11 have your exhibit sticker names on them, and Exhibit 1 is your notice of videotaped 3 deposition. 4 5 Α. Okay. If you just take a look at that, I 6 7 just want to make sure that you understand that you're appearing today pursuant to such notice 8 9 and are ready to testify pursuant to that 10 notice. THE TECHNICAL ASSISTANT: Mr. 11 12 Barnes, do you want me to go and drop that in 13 the marked exhibits folder? 14 MR. BARNES: Sure. 15 16 (Thereupon, Deposition Exhibit 1, 17 Notice of Videotaped Deposition of 18 William DiFrangia, was marked for 19 purposes of identification.) 20 21 So yes, Exhibit -- Exhibit 1 for Α. 22 myself, yes. 23 Okay. Have you ever been deposed 0. 24 before, Mr. DiFrangia? 2.5 Α. No, I have not.

Page 14 Have you ever testified in a hearing 1 2 or a court proceeding? 3 Α. Yes. How many times? 4 0. 5 Hearings, maybe ten. Court proceedings, probably at least a hundred. 6 7 A hundred times? 0. 8 Α. Yeah. 9 Now, is that in connection -- are 10 all of those in connection with your current 11 duties at the Board of Pharmacy? 12 Some are with the current duties. 13 A lot of them have occurred with my prior 14 employment. 15 0. Okay. Since you've never been 16 deposed in civil litigation, I'll just tell you, 17 generally, I'll ask the questions. Please wait for me to finish asking my question. If you 18 19 don't understand it or need it explained or 20 didn't hear it quite right, please tell me and 21 I'll attempt to restate it for you. But if you 22 don't ask me, is it fair that I can assume that you understood it and have no problems 23 24 understanding the full nature of the question? 2.5 Α. Yes.

Q. Okay. The court reporter will be taking down all of your responses, so be careful not to respond by nodding your head or shaking your head because she may not see that, so try to verbalize as many -- all of your responses if you can.

And then, finally, if at any time you need a break to talk with your counsel, Mr. Appel, let me know and we'll take a break so that you can do that. Okay?

A. Okay.

2.2

- Q. This is a remote deposition due to the pandemic. If at any time you experience any technical difficulties, let us know and we'll try to correct them, but during the deposition you're not to receive any texts or e-mails or other types of communications that relate to your testimony. Okay?
  - A. Okay.
- Q. Are you alone at your present location with respect to being deposed today?
  - A. Yeah. I'm in my office by myself.
- Q. Okay. What did you do to prepare for your deposition today, Mr. DiFrangia?
  - A. I had reviewed the exhibits that

Page 16 were sent to me and we had a few prior 1 2. preparation events with, you know, our in-house 3 counsel, reviewed my work history and my 4 resume. 5 Okay. Which counsel -- when you say Ο. "in-house counsel," are you talking about 6 7 counsel for the Board of Pharmacy? 8 Α. Yes. 9 Would that be Mr. Appel and other 10 lawyers for the Board of Pharmacy? 11 Α. Yes. 12 Have you had any communications in 13 connection with your deposition with any counsel 14 in the litigation, either the Defendants, the pharmacy Defendants' counsel, or the Plaintiffs' 15 16 counsel, which are counsel for Lake and Trumbull 17 Counties? 18 Α. No. 19 Have you ever had any communications 20 with any lawyers in this litigation representing 21 the counties, Lake and Trumbull County, or any 22 of the pharmacy Defendants? 23 Α. No. 24 Could you give us a brief summary of 0. your educational background, starting with 25

Page 17 1 college? 2. Α. Sure. 3 I have a Bachelor's degree in criminal justice from Youngstown State 4 5 University and I obtained that in December of 2005. 6 7 Q. Okay. MR. BARNES: My screen just turned 8 9 into a green icon. 10 THE TECHNICAL ASSISTANT: I muted 11 the phone. If you two continue to speak, it 12 will go away. 13 MR. BARNES: Okay. 14 Mr. DiFrangia, you got your Ο. 15 Bachelor's degree in December of '05. Have you 16 done any graduate work after your undergraduate 17 degree? 18 No, not through any type of Α. 19 university; however, I did go through the Peace 20 Officers -- Peace Officers training through 21 Youngstown State University. So sometimes that 22 is considered graduate coursework. 23 Did that result in a certificate or Ο. 24 any other certification or license or things of 2.5 that nature?

Page 18 Yes. I obtained a certificate 1 2. from -- from the training academy at Youngstown State and then I also obtained a certificate 3 from OPOTA for certification. 4 5 I'm sorry. You said for -- for what certification? 6 7 It's through OPOTA, the Ohio Police Officers Training Association, and that's for 8 9 just certification of being a police officer. 10 Ο. I see. 11 And did you become a police officer 12 after going through this training? 13 Α. Yes. 14 And when did you become a police 0. officer? 15 16 June of 2006. Α. 17 And for whom did you become a police Q. officer? 18 19 The city of Canfield. Α. 20 All right. And how long were you a Q. 21 police officer with the city of Canfield, Ohio? 2.2 Α. Through November of 2016. 23 Oh, so ten years? 0. 24 Α. Yes. 2.5 And what generally were your duties Q.

Page 19 1 in that ten-year time period? Were you always a 2. police officer or were you promoted to detective or things of that nature? 3 Yes. I worked as a patrol officer, 4 5 I worked as a school resource officer for one year, I was assigned to a multi-jurisdictional 6 7 drug unit for about five and a half years, and ultimately I was promoted to a detective. 8 9 0. Okay. How long were you a patrol 10 officer and where were you a patrol officer? 11 I was a patrol officer for Canfield 12 Police Department in the city of Canfield, and 13 that designation pretty much lasted from when I was sworn in in 2006 up until February of '16, 14 15 and then I was promoted to detective in 16 February of '16. 17 Q. Okay. And where is Canfield? What 18 county is that in? 19 It's in Mahoning County. Α. 20 Mahoning. Q. 21 And what is the county seat of 22 Mahoning County? I think it's Canfield. I'm not --23 Α. I'm entirely not sure. Sorry. 24 25 Is Mahoning geographically -- is it Q.

Page 20 on the border of Pennsylvania? 1 Α. Yes. And is it above Trumbull? 3 Ο. No. It's below Trumbull. 4 Α. 5 Right below Trumbull? Ο. 6 Α. Yes. 7 Did your work cause you to do 0. anything with respect to activities that were 8 9 going on in Trumbull County? 10 Α. Yes. Not very often, but it did. 11 Okay. Did you do any drug work as a 0. 12 patrol officer in that time period, that 13 ten-year time period? 14 Α. Yes. 15 0. As a patrol officer I'm focusing on. 16 Did you do street drugs, that kind of thing? When I was a patrol officer, 17 Yeah. Α. 18 assigned -- I was assigned to a 19 multi-jurisdictional drug unit, but, you know, 20 other than that, proactive drug enforcement, 21 you know, just for proactive traffic stops and 2.2 that sort of thing. 23 Q. I see. 24 While you were working as a 2.5 Canfield police officer, were you able to

Page 21 observe illegal drug activity in Mahoning -- in 1 or around Mahoning County? 2. 3 Α. Yes. What, in your experience, were the 4 5 types of drug problems you observed as a police officer in that time period? 6 7 It was predominantly heroin and prescription medication, opiates specifically, 8 9 and cocaine and marijuana. 10 Were you able to -- did you 11 investigate those types of crimes involving 12 heroin, prescription drugs, cocaine and 13 marijuana? 14 Α. Yes. 15 Were you able to determine the 16 sources of those types of drugs? Were they 17 coming into the county from outside the county? 18 Α. Yes. For the illicit street drugs, 19 they generally did. Your prescription 20 medications, it was typically an individual 21 that was prescribed the medication. 2.2 Ο. Okay. But with respect to heroin, 23 was that coming in from -- were you able to 24 observe as a police officer it coming in from specific sources, like Detroit, Mexico, New

25

Page 22 Jersey, things like that? 1 2. Α. Yeah. Through our investigations, 3 generally Columbus seemed like a -- a frequent destination that heroin was coming in through, 4 5 Akron, sometimes New York. Did you ever observe foreign 6 7 sources, like Chinese fentanyl, Mexican fentanyl, Mexican heroin, things like that? 8 9 Α. Nothing that I could definitively 10 say came from a foreign source. 11 By that you mean a foreign country? Ο. 12 Α. Yes. 13 Ο. And then you said you were a school 14 resource officer for approximately one year? Yes. 15 Α. 16 What did that involve and what 0. 17 school were you at? 18 I was assigned to Canfield High School, and really it was to, you know, have a 19 20 presence of the police department within the 21 school, ensure safety of the students and 22 staff, enforce any -- any criminal violations, and assist the school with discipline when 23 24 needed. 25 Okay. And then after that you were Q.

Page 23 assigned to this multi-jurisdictional drug unit 1 for about five and a half years you said? 3 Α. Yes. And what was the name of that drug 4 0. 5 unit? Α. The Mahoning Valley Drug Task 6 7 Force. And what types of law enforcement 8 Ο. 9 personnel were assigned to that task force? 10 Where did they come from? They came from different agencies 11 12 within the county, different police 13 departments. There was also individuals from the FBI, from the ATF, and sometimes different 14 15 state agencies. 16 What about DEA? 0. 17 They never had a person that was 18 assigned to that. We worked with them on 19 occasion, but they didn't have anyone that was 20 assigned to that unit. 21 What was the purpose of putting that 2.2 unit together? 23 To proactively investigate drug trafficking. 24 2.5 Q. And what areas did you cover on this

Mahoning Valley Drug Task Force?

2.

- A. Well, predominantly Mahoning
  County; however, if there was an investigation
  that would carry over into another county, you
  know, we would follow it there and assist other
  counties and other agencies with it.
- Q. Did any of your investigations ever include Trumbull or Lake Counties?
- A. Trumbull County, yes. And they were more investigations that I was assisting on, but we -- we would go into Trumbull County for investigations from time to time.
- Q. And on this drug task force, how big was it in terms of membership? Was it like a dozen, two dozen law enforcement personnel?
- A. Yeah. I think it was about -- about a dozen members.
- Q. And were there other police officers like yourself on that drug task force?
  - A. Yes.
- Q. And on that drug task force did you become -- as you did in your prior experience as a police officer, did you become familiar with illegal drugs, illegal drug activity in those jurisdictions?

A. Yes. So let me clarify that the experience -- the vast majority of my experience with investigating drugs was from when I was assigned to the drug task force, so, you know, any of the things that I just testified was generally from my experience being assigned to the task force. And I was still a Canfield police officer. That was just my assignment was reporting to the task force several days a week.

- Q. So those observations you gave us earlier based upon your experience concerning heroin and prescription drugs and cocaine and marijuana, that included your work on the drug task force?
  - A. Correct.

- Q. While working on the drug task force, did you work with partners on investigations? Were you assigned, for example, a group of two or three of you to certain types of investigations concerning illegal drug activity?
  - A. Yes.
- Q. Okay. And were you able to successfully prosecute individuals for illegal

Page 26 drug activity while on that task force? 1 2. Α. Yes. 3 Did any of your work on the drug task force involve prescription drugs? 4 5 Α. Yes. And in connection with those types 6 0. 7 of investigations, did you seek and obtain the assistance of pharmacies and pharmacists to 8 9 assist in those investigations? 10 Α. Yes, when needed. 11 Do you recall the pharmacies that Ο. 12 assisted the drug task force as needed? 13 Α. Yeah. You know, depending on the 14 circumstance, if we were investigating some 15 sort of deception to obtain or an illegal 16 processing investigation or someone obtaining a 17 large amount of pseudoephedrine, pharmacies 18 were -- you know, all pharmacies in the area 19 were willing to assist us when needed. 20 Would that include the pharmacy Ο. 21 Defendants in this case? 2.2 Α. Yes. 23 Giant Eagle, CVS, Rite-Aid, 0. 24 Walgreens, Walmart? 25 Α. Yes.

- Q. All right. Did you ever encounter any resistance by any of the pharmacy Defendants; in other words, saying we're not going to help the drug task force, go away?
  - A. No.

- Q. Okay. And the type of assistance that they provided, would that include -- would they call you or other members of the drug task force from time to time to provide leads on -- on potential illegal drug activity?
  - A. Yes.
- Q. Do you recall -- I represent Giant Eagle so I'm going to ask first about Giant Eagle. Do you recall Giant Eagle pharmacists providing leads to you or other members of the drug task force?
  - A. Yes.
- Q. And what about the other pharmacy
  Defendants; did they, similarly, provide leads
  to you and other members of the drug task force?
- A. Yes. I know Rite-Aid did. I can remember some times with Rite-Aid. Walmart. You know, specifically can I recall CVS and Walgreens calling me personally, not that I recall, but I can't say that that didn't happen

Page 28 1 at some point. 2. Ο. And typically what type of leads 3 would they provide? Would it relate to diversion attempts generally related to 4 5 prescription drugs? Yes. The leads varied. They would 6 7 contact us when they would have a patient come in and present what was deemed to be a 8 9 fraudulent prescription. They would contact us 10 when they had a prescriber that was prescribing 11 in a manner that may not be -- may not be 12 consistent with other prescribers in the area. 13 0. I see. So it could relate to either 14 illegal -- potential illegal activity by the 15 patient trying to get the drugs and/or the 16 prescribers who prescribe the drugs? 17 Α. Yes. 18 And did these leads result in 19 successful prosecutions of patients or 20 prescribers who were behaving illegally? 21 Α. Yes. 2.2 Now, you said you rose to the level 23 of detective in February of '16. Did you remain 24 on the drug task force now that -- after you 2.5 became a detective?

- A. No. My -- my full-time assignment with the task force ended around March of 2016. I was still there on a very limited part-time basis, but from -- around March of 2016 I was promoted to a detective, however, I was working primarily patrol shifts.
- Q. Were you doing any drug investigation work as a detective?
- A. Yes. When -- you know, when -- when I had an opportunity, and, again, I had a very limited presence at the drug task force, so, you know, I was able to do it on those days, but it was -- it was very limited.
- Q. Okay. And at some point you became employed by the Ohio Board of Pharmacy, correct?
  - A. Yes.

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- Q. And when was that?
  - A. That was November of 2016.
- Q. Okay. Why did you go to the Ohio
  Board of Pharmacy? Opportunity?
  - A. Yeah, just really a better career opportunity.
- Q. And what position did you take at the board? What was your first position?
  - A. An agent.

Page 30 1 And are you currently still an Q. 2. agent? 3 Α. Yes. So for about four and a half -- not 4 0. 5 quite four and a half years you've been an agent at the Ohio Board of Pharmacy? 6 7 Α. Yes. Did you go through training to 8 9 become an agent at the Board of Pharmacy? Did 10 they train you in some way when you got there? 11 Yeah. My -- my initial three to 12 four months consisted of a field training 13 program within the board. 14 And who did you field train with? Ο. 15 Oh, just about -- several --16 several agents within the board, several of our 17 specialists, and several of the office staff. 18 Did any of your field training 19 include Trey Edwards? 20 Yes. Α. 21 All right. By the time you went to 22 work for the board, had you become familiar with the Ohio drug laws involving how they're 23 24 regulated and drug offenses, things of that 2.5 nature?

Page 31 1 Α. Yes. 2 Ο. And you used the term "agent." that a term of art within the Board of Pharmacy 3 or does it differentiate you from other 4 5 positions like inspectors? And you used the term "specialist." Can you explain for us 6 7 generally what those different categories mean? 8 Α. Sure. 9 So our agents generally come from a 10 law enforcement background, our inspectors 11 are -- they come from a pharmacy technician 12 background, and then our specialists are 13 licensed pharmacists with the background of being a pharmacist. 14 15 Q. I see. So when you use the term 16 "specialist," you're talking about a board 17 employee who's a licensed pharmacist? 18 Α. Yes. 19 And how or why were specialists used 20 in investigations? Why would you need a pharmacist? 21 Well, they can provide a lot more 22 clinical knowledge that we, frankly, don't 23 24 possess as field agents or even specialists. 25 And have you worked with specialists Q.

Page 32 since you arrived at the board? 1 Α. Yes. 3 How many specialists does the board have presently? 4 5 I believe seven. And how many inspectors does the 6 0. 7 board have? Well, there's one in Northeast 8 Α. 9 Ohio. I could tell you that definitively. The 10 rest of the state -- I think maybe six, but 11 again, I don't know for sure the rest of the 12 state. 13 14 (Thereupon, Deposition Exhibit 5, 15 Multi-Page Document Entitled "State 16 of Ohio Board of Pharmacy July 17 Board Meeting Presentation, " 18 Beginning Bates Stamp 19 BOP MDL035385, was marked for 20 purposes of identification.) 21 2.2 Q. Okay. I'm going to show you a 23 document. It's Exhibit 5 in your second binder. 24 Α. Okay. 2.5 It's marked DiFrangia Exhibit 5. Q.

Page 33 1 Α. Yes. 2. Ο. It states on the front "July Board 3 Meeting Presentation." 4 Α. Okay. 5 The metadata for this document indicates it's dated sometime in 2017. The 6 7 reason I mention that is because we can't find a date on it otherwise. But did you attend board 8 9 meetings for the Board of Pharmacy? 10 Α. Yes. 11 And why would you attend board Ο. 12 meetings? 13 Α. Well, for the most part, they were 14 pretty much mandatory unless you had an illness 15 or some sort of prior scheduled vacation. 16 Okay. And the board is comprised of 17 approximately eight individuals; is that 18 correct? 19 Α. Yes. 20 And most of them are -- all of them Q. are pharmacists; am I correct? 21 2.2 Α. One is a general public individual. 23 Okay. And did you make 0. presentations at the board meetings for the 24 2.5 Board of Pharmacy from time to time?

- A. I don't think I ever have made a presentation for the board meetings.
- Q. Okay. Go to the second page of Exhibit 5. There's a slide showing compliance and enforcement department overview. Do you see there's kind of an organizational chart starting with the director of compliance and enforcement?
  - A. Yes.

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Q. You have chief pharmacist, then chief of investigations, administrative assistant, supervisors; then below the chief of investigations you have regional supervisors, four, and then beneath those regional supervisors, you have compliance specialists, six; agents, 18, and inspectors, four.

Do you see that?

- A. Yes, I do.
- Q. Is that -- is that consistent with your general recollection of how the board is structured in the compliance and enforcement division?
  - A. Yes, that's the correct structure.
- Q. Okay. And does that refresh your recollection about the approximate number of compliance specialists, which are pharmacists,

Page 35 1 six, statewide? Do you see that? 2. Α. Yeah, at that time in 2017. 3 Okay. And that -- you think it Ο. might have changed by adding an additional 4 5 specialist since then? I believe it has, and I think we 6 7 even had a retirement, so --8 0. Okay. I'm just interested in the 9 ballpark. So you have about six to seven 10 pharmacy specialists, about 18 agents as of 11 2017? Does that sound about right? 12 Yeah, as of 2017, but again, that 13 number is changing. 14 In what way, up or down? Ο. 15 Α. Up. 16 How many agents do you think you 0. 17 have now? 18 Α. I think we're -- if this was 18 in 19 2017, we're probably in the low 30s now. 20 Oh, wow. That's a significant Q. 21 increase. 2.2 Α. Yes. Since I've started, I kind of was at the beginning cusp of -- of a lot of 23 hiring that has happened. 24 25 All right. So you're up to about 30 Q.

Page 36 1 agents? 2. Α. Give or take, yes. 3 And inspectors, it says four. Ιs that about right for 2017, and if so, has that 4 5 increased or decreased since then? For 2017, yes, that is accurate, 6 7 and I think it's gone up since then. I'd say it probably has increased by two. 8 9 0. Okay. If you go to the fourth page 10 of this exhibit, two pages after the chart that 11 we just saw, there is a compliance and 12 enforcement map, field staff territory map. Is 13 that accurate? Does that accurately show that the board breaks its staff down into four 14 15 geographic quadrants in the state of Ohio? 16 Α. Yes. 17 Northwest, northeast, southwest and Q. southeast? 18 19 Α. Yes. 20 And personnel are designated to each Q. 21 of those four geographical quadrants? 22 Α. Yes. 23 And you're listed on the right as 24 being in the northeast quadrant; is that 2.5 correct?

Page 37 1 Correct. Α. 2 Ο. And that quadrant includes Mahoning, Trumbull and Lake Counties; is that correct? 3 Α. 4 Yes. 5 Okay. And the other is -- you have 0. 6 a couple specialists in there, Joann Predina, 7 Katie Stable (phonetic)? Α. Katie Stabi. 8 9 0. Stabi. These are two pharmacist 10 specialists that assist in your investigations; is that right? 11 12 Α. Yes; however, Joann Predina has 1.3 retired. 14 And has she been replaced? Ο. 15 Α. No. 16 Okay. But the agents assigned to Ο. 17 this northeast quadrant include you, John Bonish, Trey Edwards, Thomas Williams, Greg 18 19 Whitney, and an additional agent is Michael 20 Reese but also an inspector, Ginger Redway; is that right? 21 2.2 As of that time in 2017; however, 23 Michael Reese is no longer with the agency; 24 Ginger Redway, no longer with the agency; Greg 25 Whitney, he has also since retired.

- Q. Have they been replaced by others?
- A. Yes. Two -- there's been a few agent positions that have been replaced, but the inspector has not.
- Q. Okay. If you flip about five pages later, there's a page that has a Bates stamp BOP on the bottom right with the ending digits 393.
  - A. Okay.

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Q. It says, "Roles and Responsibilities of Specialists, Agents & Inspectors."

Do you see that?

- A. Yes.
- Q. All right. So again, to reorient, this is a presentation to the Board of Pharmacy. Was the purpose of this presentation, to your understanding, to let the board know what roles each of these types of employees was serving with the board, specialists, agents and inspectors?
  - A. Yes.
- Q. Okay. If you flip the page, we have -- the next several pages have compliance specialists and then, after that, agents, and then inspectors. I just want to make sure I understand what this information means.

Page 39 For compliance specialists, is this 1 2 showing the types of investigations and the types of inspections that compliance 3 specialists, the primary duties relate to? 4 5 Α. Yes. Okay. And then the same for agents. 6 0. 7 As agents your responsibilities included, on the investigation side, criminal investigations, 8 9 theft of drugs, illegal processing, drug 10 trafficking, deception to obtain dangerous 11 drugs, overdose, suspicious deaths, minimum qualifications of a terminal distributor. 12 13 think that's a warehouse distributor. Is that 14 right? 15 Α. Yes. 16 All right. Illegal sales and Ο. 17 purchases, drug security, impaired pharmacists, interns and technicians, unprofessional conduct, 18 19 violation of board orders, OARRS complaints, and 20 operating or practicing without a license. Is 21 that -- that's a pretty wide scope of 22 responsibilities in terms of investigations. Ιs that accurate? 23 24 Yes, that's accurate. Α. 2.5 Q. Okay. And then the types of

Page 40 inspections you did were pain management 1 2. facilities, wholesalers, Suboxone clinics (outpatient), virtual wholesalers and 3 manufacturers, third-party logistics companies, 4 5 dog trainers and retail pharmacies. Those are 6 the types of inspections that came within your 7 field of -- your scope of duties as an agent? 8 Α. Correct. 9 What's a pain management facility? 10 It would be a prescriber's office Α. 11 that prescribes controlled substances to over 12 50 percent of their patient population. 13 Ο. So in the state of Ohio prescribers 14 are allowed to distribute prescriptions right out of their offices? 15 16 Well, typically they're issued by 17 way -- yeah, they'll issue a prescription to a 18 patient and then the patient goes and gets the 19 medication filled from a pharmacy. 20 I see. And do you have actual Ο. 21 experience inspecting pain management 2.2 facilities? 23 Α. Yes. 24 Can you identify any of the pain Ο. 25 management facilities that you inspected or you

Page 41 1 have inspected? As far as the doctors' offices or 2. Α. the doctors? 3 Well, I guess that would be -- I'm 4 5 not thinking about it correctly. You describe these as essentially prescriber offices, pain 6 7 management facilities. I was thinking of pain management clinic, but that's probably why we're 8 9 not on the same page. 10 Are you familiar with the term 11 "pain management clinic"? 12 Well, we classify pain management Α. 13 clinic as a -- as a doctor's office, pain 14 management facility -- kind of classify it all 15 together. 16 Okay. And you -- you've actually 0. 17 done those inspections of those -- these pain 18 management facilities and clinics? I'll just 19 add "and clinics" on there. 20 Yes, I have. Α. 21 In your experience with the board or 22 with your prior experience as a detective and 23 police officer, do you recall any pain 24 management facilities or clinics being 25 investigated and prosecuted?

	Page 42
1	A. Yes.
2	Q. Which ones do you recall?
3	A. There was a doctor Dr. Paloski,
4	he was licensed as a pain management facility.
5	He was in Mahoning County.
6	Q. Okay. Any others that you remember?
7	A. Yes. There was a Dr. Escobar. He
8	was also in Mahoning County. He was a pain
9	management clinic.
10	Q. Any others?
11	A. There was an investigation. My end
12	is closed, however, I'm not sure of other
13	investigating partners that I had regarding
14	this physician, but he was in Trumbull County.
15	His name was Dr. Veres.
16	Q. How do you spell that name?
17	$A. \qquad V-E-R-E-S.$
18	Q. Veres. And he was in Trumbull
19	County?
20	A. Yes.
21	Q. And was he also a pain management
22	clinic?
23	A. He was.
24	Q. And your investigation closed on
25	him?

Page 43 1 Α. Correct. And how did it close? Was he 2. 0. 3 prosecuted? He -- he had surrendered his DEA 4 5 certificate. Which meant what, he could no longer 6 Ο. 7 prescribe medicine? Well, he could no longer prescribe 8 Α. controlled substances. He still has an active 9 10 medical license from the medical board, he 11 could still practice as a physician, but he 12 cannot prescribe any controlled substances 13 without a DEA certificate. 14 And why did he lose his right to 0. prescribe controlled substances? What was he 15 16 doing? 17 Well, he voluntarily gave it up. 18 You know, there was a -- there was an 19 investigation into his prescribing by the 20 pharmacy board and also other agencies, state 21 and federal agencies, and a subpoena was issued 2.2 for some patient files by the DEA, and then through negotiations with his -- with the 23 24 United States Attorney, that was -- that was 2.5 the outcome of the case.

Page 44

- Q. I see. So he surrendered his license, but how would you describe the conduct that he was -- that led to his having to surrender his license? What was he doing? Was he issuing prescriptions that he shouldn't have or bad quantities or to fake patients?
- A. High quantities of opiate prescriptions, a large volume of patients, things of that nature, some combinations of medications that were -- that were suspicious.
- Q. Was that investigation the result of a lead from one of the pharmacy Defendants?
- A. I don't know. I don't know if we ever got a lead from any of the pharmacy Defendants on it.
- Q. Okay. Any other pain management facilities or clinics that you recall being involved with inspecting and/or investigating?
- A. As far as investigations go, those are the -- those are the three primary ones that -- that I can think of. Inspections, I would inspect each facility routinely.
- Q. And did that sometimes lead to prosecutions?
  - A. No. The inspection was just -- the

Page 45 inspection was just an administrative process. 1 You know, I would go in. There was several 2. areas of the facility that I would check. 3 would meet with the prescriber and/or the 4 5 office manager, but it was clearly an administrative action, and it's just to ensure 6 7 that all the rules and regulations are being followed as far as we can tell. 8 9 0. Okay. Getting back to this 10 presentation to the board, you also inspected wholesalers; is that right? 11 12 Α. Yes. 13 And what would that involve? Would 14 that include a warehouse where drugs were 15 stored? Did you inspect those types of 16 facilities? 17 A. Oftentimes it would be a warehouse, 18 yes. 19 And Suboxone clinics, outpatient, Ο. 20 you inspected those from time to time? 21 Α. Yes. 2.2 And also virtual wholesalers and manufacturers. What is that? What is a virtual 23 24 wholesaler and manufacturer? 2.5 Well, a drug manufacturer is just a Α.

Page 46 facility that's, you know, manufacturing any 1 2 type of dangerous drugs. But I've never 3 inspected a drug manufacturer facility. I don't have any that really lie in my area, 4 5 so --6 Q. Okay. What is a virtual wholesaler, 7 though? A virtual wholesaler is -- you 8 9 know, I'm not exactly one hundred percent sure 10 of the definition of it, but it has something 11 to do with a third-party wholesaler, but I 12 can't -- I don't have the one hundred percent 13 definition for you of it. 14 Okay. And then after -- we'll skip Ο. 15 dog trainers, although that's kind of 16 interesting. Retail pharmacies, you inspected a 17 lot of those? 18 Α. Yes. 19 And did you inspect and have you 20 inspected many of the stores, retail pharmacy 21 stores owned by the pharmacy Defendants in this 22 case? 23 Α. Yes. 24 A couple pages -- the next page Ο. lists the duties of an inspector, the types of 25

Page 47 investigations that they do and the types of 1 2. inspection -- and the types of inspections that they do; is that right? 3 4 Α. Yes. 5 So inspectors also inspect retail pharmacy locations besides nursing homes and 6 clinics and doctors' offices, et cetera; is that 7 right? 8 9 Α. Yes. 10 So there was a little bit of overlap 11 between what you as an agent did and what 12 inspectors did; is that right? 13 Α. Yes. 14 All right. And then the next page 15 of this presentation shows -- it's captioned 16 "Inspections." The next page is the inspection 17 standards. So in this presentation to the board, there's a statement of the purpose of 18 19 inspection standards, and I'll just read it 20 because I want to ask you if you agree with it. 21 "The purpose of inspection standards is to 2.2 ensure that all licensed distributors of 23 dangerous drugs (DDD) are inspected on a routine 24 and consistent basis. The timing for conducting 25 these DDD inspections will be based on the known

safety concerns associated with the individual license types and business classes. The board also expects that the inspection process will be sufficient to ensure all major areas of a DDD location are evaluated over a clearly defined period of time."

Is that how you understood the purpose of inspections by the board, including the types of inspections we just went over?

A. Yes.

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- Q. In the middle there, there's a reference to the timing for conducting these inspections being based upon the known safety concerns associated with the individual license types and business classes. What does that mean to you as an agent?
- A. Well, there's certain facilities that we try to inspect, and we put like a, you know, every 12 months, every year you want to get in there and conduct an inspection.
- Q. Okay. Are there certain facilities that get inspected more and others that get inspected less from the board's perspective?
- A. Yes. As far as, you know, our general concern is -- the places that we're in

the most, such as like a Suboxone clinic, a pain management clinic, a retail pharmacy, those are typically you want to try and inspect them every 12 months.

- Q. Okay. And is the reason for that --well, let me just ask you, what are the reasons for that? Why inspect them more than other places?
- Α. Well, probably because, you know, obviously, to start with a pharmacy, it's a -you know, they're dispensing dangerous drugs. There's, you know, a lot of public safety interest that go along with that. You know, for a pain management clinic, these are doctors' offices that are prescribing a large amount of controlled substances, typically opiates. So, again, I think there's a -there's a communal interest in ensuring that those are inspected and, you know, all the rules are being followed. And the same thing with really Suboxone clinics, because they're prescribing a controlled substance to assist in -- assist in with individuals that are addicted to opiates. So I think there's -- there's a heightened priority on those because there's a

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Page 50 public safety interest and a community interest 1 2. in those facilities to be inspected regularly. 3 I see. And so you try to inspect those facilities, including retail pharmacies, 4 5 about once a year? 6 Try to, depending on caseload, 7 casework, and, well, most recently, a pandemic. And are these inspections 8 Ο. 9 unannounced; in other words, you just show up 10 and you don't give these locations advanced 11 warning, like get ready, we're coming next week? 12 Most -- most often they are 1.3 unannounced. 14 Q. And is there an investigative reason 15 for that? 16 I think it's you want to capture a 17 true sense of how they're conducting their 18 daily business. 19 Okay. And indeed on this next page 0. 20 of this Exhibit 5 there's a reference to 21 inspections; down at the bottom, "Pain 22 management facilities, every 12 months." That's 23 pretty much what you just told us; is that 24 right? 25 Α. Yes.

Q. Okay. And then the next -- two pages after that, Bates number ending in 35401, there's -- it looks to be the different types of results of inspections. You could either get a verbal warning or you would require a written response or a citation would be issued plus a written response, or you could get suspended. Those are the four types of outcomes of an inspection; is that right?

A. Yes.

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- Q. All right. Then down into the ensuing pages of these -- of this presentation, there's a section called "Audit Process," beginning on 35407. Now, is an audit different from an inspection?
  - A. Yes.
- Q. How so? What's the difference between an audit and an inspection?
- A. So what we generally do with an audit is we -- we basically use our independent personnel and we will conduct counts of their medications, when needed, to determine if there is a greater loss or a small loss or just to determine the amount of medication that they are or are not accountable for.

Q. Now, on page 35408, "Audit Process Discussion," it says, "A mandatory audit is conducted in the event that a pharmacist or intern is responsible for the loss of controlled substances or it is determined that there was a large or significant loss."

Is my understanding correct that an audit would be triggered in those circumstances; that's typically when you do an audit, when you have a major loss or a large loss or a pharmacist or an intern is actively involved with diversion?

- A. Yeah, generally that's the guiding principle for the audit.
- Q. Okay. And so are a lot more inspections done than audits because of that?
  - A. Yes.

- Q. Okay. On page 35410 there's a listing of investigations conducted. It says, "SOBOP in the news." What does SOBOP stand for?
  - A. State of Ohio Board of Pharmacy.
- Q. Okay. Is this a listing as of 2017 of some successful prosecutions of doctors and pharmacists in the state or by the board as of that point in time?

Page 53 Α. 1 Yes. 2. Ο. Were you involved in any of these investigations and prosecutions? 3 Yes. The Dr. Paloski 4 Α. 5 investigation. That's the one you referred to 6 0. earlier? 7 8 Α. Yes. 9 What about Jacklyn Cropper, a Ο. 10 pharmacist in Trumbull County; were you involved in that? 11 12 Α. No. 13 Do you have any knowledge about that 14 investigation and prosecution other than what's listed here? 15 16 I think I'm familiar with it. It 17 was before I was with the board, but I had no involvement with it. 18 19 Okay. The last section of this 20 presentation deals with Rx alerts -- Rx eAlerts 21 actually. What is an Rx eAlert? 2.2 I think it was a system that was 23 set up to -- to alert pharmacies or pharmacists 24 of fraudulent prescriptions, but it's -- it's not implemented. I don't think it's ever been 25

implemented.

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- Q. Okay. In your experience -- and you've outlined it well for us -- what are the types of diversion that you've seen of prescription drugs? What form of -- forms of diversion have you seen as a police officer and as a board agent?
- A. I think I've seen -- seen instances where people will illegally process a prescription to obtain medication, where they will deceive prescribers to obtain medication, where an individual will, maybe if they have prescriptive authority, prescribe medication to themselves, a pharmacy -- a pharmacist or pharmacy technician will steal medication from the pharmacy, and ultimately when a prescriber is prescribing medication that's outside the normal scope of their practice.
- Q. Have the forms of diversion changed over time in your law enforcement experience? I mean, do criminals respond and evolve as investigations respond and evolve?
- A. Yeah, I think they do. You know, back in the early 2000s deception to obtain a dangerous drug happened much more than it does

Page 55 1 now. 2. Q. So that type of diversion has 3 decreased. What, in your experience, is the cause of the decrease? 4 5 My opinion is that it's due to pharmacists and prescribers utilizing OARRS. 6 7 And so the criminal activity or the 0. deceptive activity has moved from that type of 8 9 deception to new forms of deception; is that 10 right? 11 I don't know that there's really 12 any new forms, but deception to obtain, seeing 13 multiple prescribers, has been on the decrease ever since the early 2000s. 14 15 Q. And you attribute that to OARRS, the 16 OARRS --17 Yes. Yes. Α. 18 What about other types of diversion? Q. Have you seen trends increase or decrease over 19 20 time or change over time? 21 Yeah. I think -- I personally 22 think that prescribing of opiates has decreased 23 quite a bit probably in the past ten years. 24 And is it the same reason? Ο. Is it 25 the prevalence of the OARRS database?

Page 56

- A. Yes. I think it's that and it's also, you know, prescribers see other prescribers get in trouble for doing something that they do similar and, frankly, they don't want it to happen to them.
- Q. Okay. And so what are the current primary forms of diversion? If those types of diversions and prescribing of opiates have decreased, what are you seeing now as an agent? What are the problem areas?
- A. The thing that I deal with the most is theft of drugs, and that can be -- again, it could be a pharmacist, pharmacy technician, a nurse, it could be a doctor, it could be really anyone that has access to any type of drug stock.
- Q. Okay. And in your current position do you get into investigations of, you know, major drug trafficking, like, you know, fentanyl coming in from out of state, things of that nature, or are you more in the pharmacy regulatory area now?
- A. Yes, primarily pharmacy regulatory.

  As far as fentanyl, there's -- there's still a

  pharmaceutical grade fentanyl patch, which

would fall into the regulatory issue with the pharmacies, but there's also the, you know, illicit fentanyl that's coming from some sort of, you know, out-of-country clandestine lab, so with that type of fentanyl we don't get involved in those types of -- those types of investigations.

- Q. I see. In your investigations of these doctors like Dr. Paloski -- Paloski I should say -- do they take a long time, years, for example?
  - A. Generally, yes.

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- Q. And in those investigations do you typically need to pull in a specialist, a pharmacist specialist at your agency in order to assist from the clinical aspects of the investigation?
  - A. We do from time to time.
- Q. Approximately how many inspections of retail pharmacy locations have you conducted, Agent DiFrangia, in your experience, four and a half years of experience at the board?
  - A. Total, I would say over a hundred.
- Q. And have any of those resulted in criminal investigations of the pharmacy or the

Page 58 pharmacists resulting in successful 1 2. prosecutions? 3 The inspections are generally Α. just an administrative review. You'd have to 4 5 really kind of see something really egregious that an inspection would transmit into a 6 7 criminal proceeding. I see. Before you go in to do an 8 Ο. 9 inspection of a pharmacy, do you look at the 10 past inspection history of the pharmacy or maybe 11 the last couple of inspections? 12 Α. Yes. 13 And why do you do that? I want to see who was there last. 14 15 I don't want to go to a pharmacy that, you 16 know, someone conducted an inspection last 17 month on, and then I also want to see if there 18 was any -- any corrective action given last 19 time, because those are areas that I will make 20 sure that I review to ensure that, you know, 21 they have responded adequately to the 2.2 corrective action. In terms of the two counties that 23 Ο. 24 are the Plaintiffs in this case, Lake and Trumbull County, have you done any inspections 25

Page 59 1 in Lake County? 2. Α. I don't think so, not that I -- not that I recall. 3 But you have performed inspections 4 5 in Trumbull County? 6 Α. Yes. 7 Have you performed a lot of Ο. inspections in Trumbull County? For example, I 8 9 know that you've inspected four Giant Eagle 10 pharmacies in Trumbull County. Is that about 11 right? 12 Well, from what I saw in the 13 packet, there's four reports; however, some of those aren't inspections. Those are merely 14 15 property receipts. 16 Okay. And what is a property Ο. 17 receipt? Is that something where you go in and 18 you take records from the pharmacy for your 19 investigations? 20 Α. Yes. 21 All right. So back to my question. 22 You've done inspections in Trumbull County you told us. I'm just trying to get a sense of --23 did you inspect all of the pharmacy defendant 24 stores, Giant Eagle, Rite-Aid, Walmart, 25

Page 60 1 Walgreens and CVS? 2. In Trumbull County? Α. 3 Ο. Yes. No, I did not inspect every single 4 Α. 5 one of those in Trumbull County or even some of those pharmacies, like a Walmart in Trumbull 6 7 County I've never conducted an inspection at. That would be another agent in the 8 0. 9 northeast region that would do that? 10 Α. No. It would be me -- it would be 11 my responsibility; however, I just have never 12 gone into a Walmart in Trumbull County to 13 conduct an inspection. 14 Have you ever gone into a Walmart to 0. 15 inspect? 16 Yes. I have when I was training, 17 when I was still doing training. 18 Q. Okay. Before -- besides looking at 19 the past inspection reports, do you take a look 20 at OARRS, the OARRS database, for the pharmacy 21 to get a sense of volume, types of drugs being 22 dispensed, things of that nature? 23 Typically with just a random Α. 24 inspection, no, I do not inspect -- I do not 2.5 review OARRS.

- Q. All right. But the board -- you know that the pharmacies are reporting on a daily basis into the OARRS database?
  - A. Yes.

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- Q. So the board -- any time an inspection occurs, the board has the ability to check that pharmacy location's dispensing activities for all drugs before going in for an inspection; is that right?
  - A. Yes. We have the ability to.
- Q. Okay. Are you familiar with the Ohio Administrative Code, the regulations governing pharmacies and pharmacists?
- A. Yes. Which code -- which code specifically are we discussing?
- Q. I'm talking about the Administrative Code Sections 4729 related to pharmacies and pharmacists.
  - A. Yes.
- Q. Okay. Is that part of your role as an agent, to be familiar with those regulations?
  - A. Yes.
- Q. Okay. And you know that those regulations have certain requirements. One is called the security requirement, to have

Page 62 effective and approved controls and procedures 1 to deter and detect theft and diversion of 3 dangerous drugs? Α. 4 Yes. 5 All right. And that's a regulatory 0. requirement in the Ohio Administrative Code, 6 7 correct? 8 Α. Yes. 9 And according to those provisions, 10 pharmacies must be in substantial compliance 11 with those provisions based upon a multitude of 12 factors, including the type of activity being 13 conducted, the nature of the location, and other 14 factors; is that right? 15 Α. Yes. 16 And so when you did your 17 inspections, was one of the purposes of your inspections to make sure that the pharmacists --18 19 pharmacies were complying with that security 20 requirement? 21 Α. Yes. 2.2 Ο. Okay. Did you work from time to time with pharmacy loss prevention departments 23 24 for any of the pharmacy Defendants? 2.5 Α. Yes.

- Q. And first I'll ask about Giant Eagle. Did you work with Giant Eagle's loss prevention department, and specifically a gentleman by the name of Rick Shaheen, who is in charge of Giant Eagle's loss prevention -- pharmacy loss prevention department?
  - A. Yes, I've worked with Mr. Shaheen.
- Q. And with respect to the other pharmacy Defendants, did you work with their loss prevention departments?
- A. I have -- yes, I have. Walmart, there was -- he was a district pharmacy manager that I have worked with, but as far as a loss prevention person, that would just be like the store-level person that I've worked with on occasion.
- Q. Okay. Any of the other pharmacy Defendants that you can recall?
- A. Yes. Each of the other pharmacy
  Defendants I have worked with their loss
  prevention, their pharmacy loss prevention
  personnel.
- Q. Did you view it as a good internal control for the pharmacy Defendants to even have a loss prevention department?

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A. Yes.

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- Q. How so? Why was that a good internal control?
- A. Well, they're adhering to our rules and, you know, you've got a pharmacy that's full of several different drugs, and not even just controlled drugs and opiates, but, you know, you have expensive medication, and I'm sure everyone has a vested interest to make sure that there's accountability for all that, not -- you know, let alone not to mention the issues of some of these drugs are extremely addictive and we want to ensure that they're being dispensed to an individual pursuant to a prescription.
- Q. I see. And do the pharmacy
  Defendants' loss prevention departments provide
  leads to you from time to time of diversion
  activities or things to investigate?
  - A. Yes.
- Q. Specifically -- I'll talk about

  Giant Eagle first. Do you recall Mr. Shaheen

  calling you from time to time and telling you

  about specific issues that had arisen in certain

  pharmacies in terms of potential diversion

Page 65 activities? 1 2. Α. Yes. 3 And were those good leads in the sense that he was, you know, being cooperative 4 5 with you and initiating law enforcement 6 involvement by saying we've got X problem at Y 7 pharmacy, we want you to be involved? Α. 8 Yes. Okay. And was that the same for the 9 other pharmacy Defendants, their loss prevention 10 11 heads or members would, similarly, provide leads 12 to you and the other board members related to diversion activities? 13 14 All except for Walmart. I don't 15 think I've ever had an instance of any type of 16 diversion regarding a Walmart employee or -- I 17 take that back. I have been notified in my prior career of improper prescribing by a 18 19 Walmart pharmacist and pharmacy tech. So I 20 stand corrected. I would say everyone has 21 contacted me at some point within my entire 2.2 career. 23 Did that -- did you view that type Ο. 24 of activity, being contacted by the pharmacy Defendants, to be a positive indication to you 25

Page 66 of pharmacies attempting to comply with the 1 2. rules by engaging with agents at the board and 3 providing leads and notice of potential diversion? 4 5 MR. WEINBERGER: Objection. 6 Α. Yes. 7 With respect to the interactions 0. with the Giant Eagle loss prevention department, 8 9 do you recall any specific examples of Rick 10 Shaheen providing leads to you concerning 11 activities at Giant Eagle pharmacies? 12 Yes. We've -- him and I have 13 investigated a few individuals that were stealing drugs from pharmacies. I've requested 14 his assistance on several other investigations 15 16 regarding, you know, a video for suspects of 17 illegal processing or anything of that nature, or even sometimes I've asked for information 18 19 of, you know, Giant Eagle Advantage cards that 20 was used to purchase a fraudulent prescription. 21 Okay. And did Mr. Shaheen -- did 22 you find him to be competent and -- as an investigator himself? 23 24 Α. Yes. 2.5 Did he assist you from time to time Q.

Page 67 in setting up video surveillance to detect 1 illegal activities? 3 Α. Yes. And did that result in successful 4 5 investigations and prosecutions of individuals? 6 Α. Yes. 7 And did he provide, when requested, Ο. Giant Eagle Advantage Card information to assist 8 9 in your investigations? 10 Α. Yes. 11 Do you recall any notable incidents 0. 12 that you worked with Mr. Shaheen involving 13 illegal activities? Does anything come to mind? 14 We've had several cases and he's 15 helped me out. I had -- had a doctor that was 16 writing prescriptions to his wife for 17 controlled substances. I believe he provided 18 the video for that. And, you know, recently I 19 had a physician that was doing something 20 similar, and he provided the Advantage Card 21 information. He's contacted me countless 2.2 amounts of times when his pharmacists have --23 have found an illegal prescription or a 24 fraudulent prescription. Generally, depending 25 on the instance, I direct them to -- I direct

Page 68 them to local law enforcement, but we've also 1 2. investigated pharmacy technicians that have 3 been diverting drugs, and, you know, him and I have successfully interviewed them and 4 5 successfully obtained, you know, acknowledgments of individuals doing that 6 7 activity. 8 Ο. I see. 9 In your engagements with Rick Shaheen and the loss -- Giant Eagle loss 10 11 prevention department, did you find them to be 12 cooperative and proactive in attempting to 13 avoid diversion and investigate and prosecute 14 diversion? 15 Α. Yes. 16 Would the same be true of the other 0. 17 pharmacy Defendants? 18 Α. Yes. 19 Do you recall at any time ever 20 believing that any of the pharmacy Defendants 21 were causing diversion themselves? 2.2 Α. Could you rephrase that? 23 Sure, and I'll break it down. 0. 24 You gave us a nice description of 25 your work with Rick Shaheen and the Giant Eagle

Page 69 loss prevention department. My follow-up 1 2. question is, did you at any time believe that 3 Giant Eagle was itself violating any of the pharmacy rules and regulations itself and 4 5 causing diversion itself? 6 MR. WEINBERGER: Objection. 7 0. You can answer. Okay. No. There was nothing that 8 Α. 9 I -- that I could think of that led me to 10 believe that. 11 What about with respect to the other Ο. 12 pharmacy Defendants? 13 MR. WEINBERGER: Objection. 14 Α. And, again, I -- I -- you know, 15 there's, again, nothing that comes to mind for 16 them. 17 18 (Thereupon, Deposition Exhibit 3, 19 E-Mail String, Beginning Bates 20 Stamp LAKE000068980, was marked for 21 purposes of identification.) 2.2 23 I'm going to direct your attention 0. to DiFrangia Exhibit 3, which is at the end of 24 your second binder. It's an e-mail marked 25

Page 70 LAKE-68980. Have you had a chance to look at 1 that, sir? 3 Α. Yes. There's a reference there to a 4 0. 5 Dr. Thomas Detesco, D-E-T-E-S-C-O. 6 Α. Yes. 7 Ο. Were you involved in investigation of Dr. Detesco? 8 9 Α. No, not in the investigation. 10 All right. But you were e-mailing 0. 11 about him and you state that "He is retired from 12 practicing in the Youngstown area, however his 13 DEA credentials are still active and have been 14 compromised." What did you mean by that in this 15 e-mail? 16 That someone had obtained his DEA 17 credentials and basically were issuing 18 prescriptions without his -- without his 19 knowledge or without his authorization. 20 Q. So that's a type of diversion 21 itself, correct? 2.2 Α. Yes. Yes. 23 At the end of that e-mail you say that -- there's a reference to coming from 24 2.5 Detroit.

Page 71 1 Do you see that? 2. Α. Yes. 3 What did you mean there? What does Ο. 4 that mean? 5 So what this -- this instance, from Α. 6 what I recall, there was a state trooper I 7 spoke with that had stopped a vehicle and the vehicle had several of these blank 8 9 prescriptions utilizing this prescriber's name 10 and prescribing credentials, and the vehicle 11 was supposedly coming from Detroit, vehicle and 12 its occupants. 13 Ο. I see. 14 In your experience at the board or 15 prior as a detective and patrolman, do you have 16 any experience with illegal drugs coming in 17 from Detroit? 18 Α. Yes. 19 Was that a problem in Trumbull or 20 Lake Counties? 21 I think for Trumbull it was, but 2.2 most of our investigations did not -- did not 23 have a Trumbull County nexus when I was a 24 policeman or when I was with the drug task 25 force, and, you know, these were kind of like

fractions that -- from what I recall at the time, there was a Warren to -- Warren, which is in Trumbull County, a Warren to Detroit nexus for -- for drug trafficking, but mostly within Mahoning County it was typically Akron, Columbus, New York, Atlanta even, it was those types of major hubs that seemed to be supplying most of the individuals we were investigating.

- Q. Okay. Let me ask you this: When you would begin an investigation of a doctor for whatever reason, would you advise the pharmacies in the area to stop filling his prescriptions, his or her prescriptions?
  - A. No.

2.

- Q. Why not?
- A. Well, a pharmacist has their -they have to exercise their own -- their own
  professional judgment in dispensing
  prescriptions, which I don't have any of their
  education, their clinical background or, you
  know, really the ability to provide them any of
  that professional judgment. So I leave the
  judgment on to them, but I -- you know, that's
  primarily the driving force for why I don't
  advise them to or not to fill prescriptions.

Page 73 1 Does it have anything to do with not 2 wanting to tip off the doctor that he's under 3 investigation? 4 MR. WEINBERGER: Objection. 5 You can answer. Ο. That -- that's -- that is a typical 6 Α. 7 outcome that could happen; however, again, I leave it up to them. I tell them utilize your 8 9 professional judgment. If they have concerns with the amount of opiates and they decide 10 11 that, you know, there's -- they don't want to 12 dispense the medication, it's completely on 13 their -- their professional judgment to do so. 14 Okay. And, in your experience, that Ο. involves a multitude of factors, is that 15 16 correct, not only just data but also other 17 things that the pharmacists will consider? 18 MR. WEINBERGER: Objection. 19 Ο. Is that right? 20 MR. WEINBERGER: Objection. 21 Α. Yes, that's correct. 22 Okay. Do you recall an Q. investigation of a doctor I believe by the name 23 of Skiffey, S-K-I-F-F-E-Y? 24 25 Α. Yes.

Page 74 Were you involved in that 1 investigation? 2. 3 Α. Yes. What -- let me ask this: Where is 4 0. 5 Dr. Skiffey located, his practice? It's in Niles, Ohio, which is in 6 7 Trumbull County. And when did you become involved 8 Ο. with the Dr. Skiffey investigation? 9 10 Α. That was April of 2019. 11 And is that an ongoing investigation Ο. 12 or is that concluded? 13 Α. It's concluded. 14 How did it conclude? Ο. 15 Α. Well, the suggested criminal 16 portion is still with the Trumbull County 17 Prosecutor's Office. As of this date, he 18 hasn't been prosecuted criminally, but I have 19 handed my investigation over to them. 20 Q. I see. 21 And what did your investigation 2.2 reveal about Dr. Skiffey? He had a live-in girlfriend that he 23 Α. 24 was prescribing a regular amount of Valium and 25 some occasional opiates to, and after

Page 75 interviewing him, he failed to document the 1 2. vast majority of those prescriptions within her patient file. 3 I see. 4 0. 5 Was that investigation open as a result of a tip or a lead from any of the 6 7 pharmacy Defendants? That was actually a complaint 8 Α. No. 9 from his girlfriend's family members. 10 And did you obtain property from a 0. 11 couple of Giant Eagle pharmacies in connection 12 with that investigation? 13 Α. Yes. 14 15 (Thereupon, Deposition Exhibit 6, 16 State of Ohio Board of Pharmacy 17 Property Receipt, dated September 18 18, 2019, Beginning Bates Stamp 19 BOP MDL2796412, was marked for 20 purposes of identification.) 21 2.2 (Thereupon, Deposition Exhibit 8, State of Ohio Board of Pharmacy 23 24 Property Receipt, dated September 2.5 18, 2019, Beginning Bates Stamp

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Page 76
                 BOP_MDL2796570, was marked for
1
                 purposes of identification.)
3
                 Is that shown on Exhibits 6 and 8?
4
           Q.
5
    DiFrangia Exhibit 6 and DiFrangia Exhibit 8, are
     these receipts showing you going to Giant Eagle
6
7
    pharmacies and obtaining pharmacy records,
     things of that nature?
8
9
           Α.
                 Yes. These are -- this is
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    documentation of me seizing those original
11
    prescriptions.
12
           Q.
                I see.
13
                 And you wanted those prescriptions
     in order to prosecute him?
14
15
           Α.
                 Yes.
16
                 Dr. Skiffey?
           Ο.
17
           Α.
                 Yes.
18
19
                 (Thereupon, Deposition Exhibit 4,
20
                 Consent Agreement Between James J.
21
                 Skiffey, DDS and the Ohio State
2.2
                 Dental Board, was marked for
                 purposes of identification.)
23
24
2.5
                 Okay. And is Exhibit 4 in the
           Q.
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Page 77 binder, DiFrangia Exhibit 4, one of the results 1 of your investigation of Dr. Skiffey? Yes, that is. 3 Α. And did Dr. Skiffey surrender his 4 0. 5 DEA registration as part of this agreement? Yes, he did. He surrendered his 6 DEA certificate. 7 Did he do anything else besides 8 Ο. 9 surrender his certificate, to your recollection? 10 No. He might have had some Α. 11 additional penalties through the dental board, but as far as I can recall, he surrendered his 12 13 DEA certificate. 14 15 (Thereupon, Deposition Exhibit 2, 16 E-Mail String, Beginning Bates 17 Stamp TRUM001765557, was marked for 18 purposes of identification.) 19 20 Okay. Look at Exhibit 2, DiFrangia Q. 21 Exhibit 2 in your binder. It appears to be some 2.2 e-mail communications between you and I think 23 it's a prosecutor; is that right? 24 Α. Yes. And includes Dr. Skiffey and two 2.5 O.

Page 78 1 others, Donna George and a pharmacist by the name of Alan Mike? 3 Α. Yes. And so these are pending criminal 4 5 prosecutions as of May and June of 2020? Correct, and they're still pending. 6 Α. 7 (Thereupon, Deposition Exhibit 7, 8 9 Barricade Inspection, was marked 10 for purposes of identification.) 11 12 0. Now, Exhibit 7 in your binder 1.3 references a so-called barricade inspection of a 14 Giant Eagle pharmacy on Elm Road in Warren, 15 Ohio; is that right? 16 Α. Yes. 17 What is a barricade inspection? Q. 18 So it's generally to just check Α. 19 the -- check the barricade, which consists of 20 the storage of the records outside of the 21 pharmacy, and then the actual outside 2.2 barricade, which, as you may have seen before, 23 it's a cage sometimes that comes down, 24 depending on the pharmacy. But, you know, we check the external locks, check the surrounding 25

Page 79 1 area, ensure only the people that have access 2 are the people by law that can have access to 3 the pharmacy. Q. I see in this inspection on page 3 4 5 of 4 you mention in this report that Giant Eagle store 1419 was the victim of a possible breaking 6 and entering during May of 2017 through a roof of an adjoining business. 8 Do you recall that? 9 10 Α. Yes. 11 So is that something that happens 12 from time to time, that type of breaking and 13 entering, going through roofs of businesses? 14 Α. Yes. 15 Did Giant Eagle cooperate with 16 investigation -- or, I'm sorry, this inspection 17 and anything related to the -- any loss related 18 to the breaking and enterings? 19 Α. Yes. From what I recall, they 20 contacted me and asked me to come out and take 21 a look. 22 Do you recall investigating a doctor by the name of Prommersberger? 23 24 Α. Yes. 25 Q. He was a podiatrist; is that right?

Page 80 1 Yes. He still is a podiatrist. Α. 2. Ο. Okay. How was that investigation 3 Were you provided a lead from started? somebody? 4 5 Yes, I was provided -- we were provided leads and -- leads, various types of 6 7 leads. 8 9 (Thereupon, Deposition Exhibit 10, 10 James E. Prommersberger, DPM Search 11 Warrant, with Attachments, 12 Beginning Bates Stamp 13 BOP\_-MDL1191777, was marked for 14 purposes of identification.) 15 16 All right. Did -- if you look at 0. 17 page 6 of Exhibit 10, DiFrangia Exhibit 10, this is an affidavit and search warrant for James E. 18 19 Prommersberger, DPM for his facility at Advanced 20 Arthroscopic Foot & Ankle Associates, Inc. in 21 Boardman, Ohio; is that right? 2.2 Α. Yes. 23 Is this your search warrant 24 affidavit? 2.5 Yes, it was mine, and there was Α.

Page 81 another agent, him and I worked on this 1 2. investigation together, and then we had someone that was actually -- we had a law enforcement 3 officer that was the affiant. 4 5 I see. And this is dated -- I'm 6 looking at the back. Why don't you tell me. 7 When approximately was this search warrant affidavit prepared? 8 9 Α. This was the end of August 2017. 10 If you look at page 6 at the bottom, 0. 11 under the section Criminal Activity Detailed, 12 beginning with paragraph 2 there appears to be a 13 listing of all of the contacts and complaints from various sources. 14 15 Do you see that? 16 Α. Yes. 17 And would you look at the paragraph 18 2(a)? On September 29th, 2014 it references you and Agent Bonish of the Board of Pharmacy 19 20 received information concerning the questionable 21 prescribing habits of Dr. James E. 22 Prommersberger from multiple registered pharmacists practicing at Giant Eagle's number 23 24 4075 located just over 1,000 feet from the 25 office of Dr. James Prommersberger. Does this

Page 82 refresh your recollection, sir, that this 1 2. investigation and prosecution of 3 Dr. Prommersberger began with Giant Eagle pharmacists? 4 5 Α. Yes. And from there your search warrant 6 0. 7 continues to list multiple subsequent contacts regarding his activities; am I right? You seem 8 9 to go in chronological order detailing each and 10 every activity and complaint that you received 11 about this doctor. 12 Α. Yes. 13 I'm going to refer you to paragraph 14 C. There's a reference to a Kroger Pharmacy 15 making a complaint. 16 Do you see that? 17 Α. Yes. 18 Paragraph D, a Walmart pharmacist 19 complaining -- I'm sorry, a pharmacy technician 20 employed at Walmart? 21 Α. Yes. That was another source of 22 Ο. complaints. Paragraph F, an employee of Walmart 23 24 pharmacy 2211, do you see that? 25 Α. Yes.

Q. And then paragraph G, Fred's Family Pharmacy, yet another source of complaint for this doctor.

Does that refresh your recollection that you were getting multiple complaints from multiple pharmacists and pharmacy employees, including Giant Eagle, Kroger, Walmart, complaining about this doctor?

A. Yes.

2.2

- Q. Okay. And what was the nature of these complaints? What was Dr. Prommersberger doing according to these complaints?
- A. Well, it seemed that these were typically patients that did not live within the geographical area and they were coming to Dr. Prommersberger's office, they were being issued prescriptions for opiates, and a lot of these patients had several -- they were -- similar prescriptions were being issued to all of them, so a lot of their drug therapies were identical, which typically is a red flag.
- Q. Okay. And did your investigation prove that to be true, that this doctor was inappropriately prescribing opioids?
  - A. Yes.

Page 84 What is the status of the 1 2 prosecution of this doctor? 3 He's been indicted through Mahoning Α. County and we're currently awaiting a trial. 4 5 And do you expect to use Giant Eagle pharmacists or Walmart pharmacists in this 6 7 prosecution and trial in any way? If the prosecutor deems it 8 Α. 9 necessary. 10 Okay. Besides providing the initial 0. 11 leads, did these pharmacies and pharmacists, 12 Giant Eagle and Walmart and these others listed, 13 did they cooperate with your investigation and 14 provide whatever records or assistance you needed? 15 16 Α. Yes. 17 I understand that you have an open 18 investigation of another pharmacy, and because it's open, I'm only going to refer to the name 19 20 once. Brown's Pharmacy? 21 Α. Yes. 2.2 Ο. And is that an independent pharmacy 23 in Trumbull County? 24 It's an independent pharmacy in Α. 2.5 Mahoning County.

Page 85 That's a pending investigation, it's 1 Ο. 2. open; is that right? It's open and active. 3 Α. Okay. I'm going to not ask any 4 0. 5 further questions because I've been advised that it's open and active. 6 7 Α. Thank you. 8 Ο. Sure. 9 Have you received leads from 10 Rite-Aid from time to time concerning potential diversion activities? 11 12 Α. Yes. 13 Ο. Have you worked with Rite-Aid's loss prevention department to investigate and 14 prosecute diversion activities? 15 16 Α. Yes. 17 Would that include things like Q. deception and stealing of drugs? 18 19 Α. Yes. 20 Did Rite-Aid appear to have a Q. 21 proactive and competent loss prevention 22 department that worked with you? 23 Α. Yes. 2.4 (Thereupon, Deposition Exhibit 9, 2.5

Page 86 1 One-Page Document Entitled "Prescription Drug Investigations -3 Techniques and Workflow, " was marked for purposes of 4 5 identification.) 6 7 0. If you look at DiFrangia Exhibit 9, this is a document captioned "Prescription Drug 8 9 Investigations - Techniques and Workflow." 10 Do you see that? 11 Α. Yes. 12 0. What is this exactly? I was trying 1.3 to -- and the only reason I put it in here is 14 because I couldn't get a full grasp on what this -- what this is. 15 16 This looks like an internal 17 document. It's just giving some guidance on 18 how to approach determining whether you have a 19 prescribing issue with a prescriber. 20 Is this kind of like a general Ο. 21 checklist of things to do for agents when they 2.2 receive a tip, how to go about it? 23 Α. Yes. 2.4 Does the Ohio Board of Pharmacy have Ο. 2.5 subpoena powers and the right to go into the

OARRS database as part of its investigations?

- A. Yes. So we have administrative subpoena powers through the Ohio Board of Pharmacy and then we are able to access OARRS data for investigations.
- Q. And when you access OARRS data as part of investigations, you're entitled to look at all of the OARRS data, correct, not just limited pieces of the data; is that right?
  - A. Correct.

2.

- Q. Indeed that's one of the reasons

  OARRS was created was to assist law enforcement
  to get all of the prescription data from all of
  the pharmacies so that there would be a database
  that law enforcement could look at to see
  activity across pharmacies throughout the entire
  state, right?
- A. Yes. Part of it is assisting law enforcement, but it's also assisting prescribers and pharmacies and pharmacists.
- Q. Right. So when a doctor writes a prescription, part of his duties is to check OARRS for certain types of prescriptions; is that right?
- 25 A. Yes.

- Q. So even before the prescription is filled out, the doctor is supposed to check
  OARRS for prescribing to the specific patient in front of him; is that right?
  - A. Yes.

- Q. So when the doctor checks OARRS before writing the prescription, is he able to see other prescriptions that this same patient has obtained, for example, another doctor across town or another doctor in the practice, things of that nature?
- A. Yes. They can see other prescriptions for controlled substances only.
- Q. Okay. No matter who issued them?

  For example, it's not just me, the doctor, if I check on this patient, I'm not just going in and seeing what I prescribed to him, I'm seeing what other doctors have prescribed to him in terms of controlled substances?
  - A. Correct.
- Q. But can the doctor look at other doctors prescribing other than that patient? For example, if a doctor saw that Dr. -- that his patient in front of him was -- had seen Dr. Smith a week earlier and got the same

Page 89 prescription, am I right that the doctor would 1 2. only see that this patient got the same 3 prescription from some other doctor? Yes, that's correct. 4 Α. 5 But if he wanted to -- if that 0. doctor wanted to look at Dr. Smith's general 6 7 prescribing habits, he wouldn't be able to do that, right? 8 9 Α. Correct. 10 But the board agents could do that? 0. 11 Α. Yes. 12 Q. That's the way that's set up? 13 Α. Yes. So the doctor is limited to the 14 Ο. 15 patient's controlled substance prescription 16 history only when he writes the prescription? 17 Α. Now, a doctor can also review Yes. 18 their own prescribing through OARRS, but that's 19 it. 20 Okay. So once the doctor reviews Q. 21 OARRS and writes the prescription and the 22 patient goes to -- picks a pharmacy to get it 23 filled, what can the pharmacist see when he 24 accesses OARRS? 25 Α. They can -- they can see the same

Page 90 thing, just the patient's history of controlled 1 substances that have been dispensed to them. 3 So the pharmacist doesn't have the ability to say I want to see Dr. -- both 4 5 doctors' complete histories of what they're 6 doing? 7 Correct. Through OARRS they 8 cannot. 9 0. Okay. And nor do the pharmacies 10 have subpoena powers, like the agents of the 11 board have; is that right? 12 As far as I know, they do not have 13 subpoena powers. 14 Okay. And, in your experience, do you understand that it's the board's 15 16 responsibility to investigate diversion using 17 the OARRS database, that that's their primary 18 responsibility? 19 Α. Yes. 20 MR. BARNES: We've been at it an 21 hour and 45 minutes. Why don't we take a 2.2 ten-minute break. 23 THE VIDEOGRAPHER: Going off the 24 record at 10:43. (Recess had.) 2.5

Page 91 1 THE VIDEOGRAPHER: We are back on the video record at 10:54. 2. BY MR. BARNES: 3 Mr. or Agent DiFrangia, we're back 4 0. 5 on the record after a short break. I want to switch now to the licensing requirements set 6 7 forth in the Ohio regulations related to pharmacies. Are you familiar with those 8 9 regulations? 10 Α. Yes. 11 Am I correct, sir, that Ohio 12 regulations call a pharmacy a terminal 13 distributor? Is that the regulatory language, a 14 TDDD? Yes. Go ahead. 15 Α. 16 It's a TDDD, terminal distributor of Ο. 17 dangerous drugs? 18 Α. Yes. 19 Known to laymen as a pharmacy? 0. 20 Yes. Α. 21 Okay. Now, pharmacies have to be 0. 22 licensed in Ohio; is that correct? 23 Α. Correct. 24 Ο. And in order to get that license, they have to apply to and be approved by the 25

Ohio Board of Pharmacy?

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- A. Yes.
- Q. And in order to go through that process, they have to be inspected and reviewed by board employees?
  - A. Yes.
- Q. Can you describe for us what those inspections and reviews entail? I guess what I'm getting at is, how easy is it to get a board license? Is it send in a \$25 check and give them your name and you can open up shop or is it more rigorous than that?
- Α. No. It's more rigorous. There's an application process. There's a background check that has to be conducted on ownership, and then, you know, if the background check is consistent, FBI BCI records check, and then also internal background check. So if this is a person that maybe we have dealt with in some capacity, there's going to be a record of it, and then the license -- the application is processed by our licensing department. Ιf everything is okay, it's sent out to an agent or an inspector, generally an inspector at this point, and they will go conduct a -- you know,

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Page 93 an initial barricade inspection. If this is a pharmacy that is just -- you know, just getting up and going, maybe they occupied new space or they built a new building, at that point we go in and ensure that they have the bare bones basic things to run a pharmacy, such as adequate locks, you know, an alarm system of some sort, access is limited to just pharmacists, and, you know, they have some 10 systems in place to start obtaining drug orders 11 from different wholesalers. So it's -- it's a 12 rigorous process. And then, you know, 13 there's -- there's a fee that has to be paid. And, you know, at that point, once you're up 14 15 and running, then you basically agree to future 16 inspections by us. You agree to, you know, 17 ensure that all the rules and regulations are followed. 18 19 Okay. And you have to maintain that 0. 20 license, right? It's not once you're licensed, 21 you're forever licensed, you have to renew your 22 license from time to time; is that right? 23 Correct. It needs renewed -- I Α.

> And in connection with those Ο.

think it's either every year or two years.

renewals, are you -- is the licensee subject to further reviews and inspections by the board?

- Yes. They -- each time they have Α. to answer an application, they have to attest to the truthfulness of the application, and it's resubmitted to the board. And then, you know, inspections, they're not based on whenever they reapply. The inspections can come at various amounts of times. Sometimes it's based on you haven't been inspected in a while and a proactive inspection occurs, or maybe there's an investigation, which could be several different things, consumer complaints, you know, maybe an error in dispensing or something of that nature, but generally, at the end of an investigation, we'll go in and conduct an inspection at the pharmacy.
- Q. I see. So the inspections aren't triggered by renewal of licenses but inspections are considered as part of the renewal process?
  - A. Yes.

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- Q. So can a bad inspection result in loss of license?
- A. It would have to be really egregious.

Page 95 But that's a potential outcome, 1 Ο. 2. correct? 3 Α. Yes. I think in your Exhibit 5 we had 4 5 those four levels of potential results of inspections, verbal warnings, written responses 6 7 required, citations or summaries, suspensions. Do you remember that? 8 9 Α. Yes. 10 So if the inspection is bad, you Ο. 11 could get suspended, correct? 12 Α. Yes. 13 Okay. So there's a range of 14 outcomes. So the inspections themselves, would 15 you agree, are they an important part of the 16 licensing process and the renewal of the 17 licensing process? 18 I think it's an important part, but Α. again, it's -- it's just not solely based on 19 20 that renewal. You know, if there's an 21 ownership change in the renewal or they change 2.2 their name or they change their business 23 structure, that could prompt an inspection, but 24 it's just -- very rarely is it based on the 25 fact that they did their annual or biannual

Page 96 1 renewal. 2. Ο. Okay. All right. So the pharmacy itself has to be licensed and go through that 3 rigorous process and then go through renewal 4 5 processes, but there's further licensing involved at a pharmacy location, correct? 6 7 Α. Yes. The pharmacist has to be licensed? 8 0. 9 Α. Yes. 10 Is that right? Ο. 11 Yes. Α. 12 Who else has to be licensed in a 0. 13 pharmacy according to the State of Ohio? 14 Pharmacy technicians also. 15 0. Is that something you look for when 16 you go for your inspections, make sure that 17 those licenses are displayed and current? 18 I ensure that the -- all parties Α. 19 are properly licensed. They actually don't 20 have to have their licenses displayed anymore, but we do check to make sure that they are 21 22 properly licensed. 23 And does the board license the 0. pharmacists themselves? 24 2.5 Α. Yes.

Q. And in order to become a -- to get a license as a pharmacist from the board, what are the requirements to your understanding?

It requires -- it requires, obviously, the education needed. There's -there's different education requirements for it, and then they have to apply, they have to submit a records check, and they have to answer honestly on their application. And our licensing department does the same -- does the same review of those applications, checks to ensure that this is an individual that we have somehow investigated in the past or something of that nature, and then -- then their license is issued, and it is renewed every two years, and they, similarly, have to attest that, you know, they haven't committed any crimes and they're not -- you know, they're practicing in the best methods and they've kept up on all their required education items.

Q. Okay. So the renewal department -- I guess your licensing department takes care of that, the original licensing of pharmacists and the renewal of pharmacists' licenses?

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Q. And techs have to be -- pharmacy techs have to be licensed. Is that a more recent development? Is that like 2016 or '17?

Am I recalling correctly?

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- A. Yeah. I think it was -- I think it was 2017 at some point.
- Q. Why did the board decide to license techs?
- A. I think there are -- there are several different reasons. One that I can imagine is that, you know, if you have someone that potentially diverts medication, there's -- there's an extra oversight over them. This way they just can't go to another pharmacy and start working as a technician. We control that. We dictate their license status, and, again, it's just really an extra -- extra -- extra arm that's ensuring that someone, you know, is practicing in their best faith. And I think it brings a little bit more professionalism to the career of a pharmacy technician.
- Q. Since that licensing for techs requirement went into effect, have you seen it have any beneficial effect on diversion?

Page 99 Yes. 1 Α. 2. Ο. How so? 3 Well, as I mentioned, what it does Α. is if we -- if we determine that there's a 4 5 pharmacy technician that's diverting drugs or if they have an addiction or for whatever 6 7 reason that they're a threat to public safety, we're able to revoke or suspend their pharmacy 8 9 technician license. This way if -- let's say 10 they're working at Giant Eagle, they get 11 terminated. They can't go to an independent 12 pharmacy that's maybe in another county and 13 then work as a pharmacy technician there 14 because their license is suspended. 15 0. I see. Okay. So it has had a good 16 effect on decreasing diversion by requiring 17 techs to be licensed? 18 Α. Yes. 19 Okay. Have I covered everybody or Ο. 20 anybody and everybody that needs to be licensed 21 at these retail pharmacy locations? We have the 22 pharmacy itself and we have the pharmacists and 23 we have the pharmacy technicians. Is there 24 anybody else that needs to be licensed? 2.5 If there's a pharmacy intern, Α.

Page 100 they're also licensed. 1 2. 0. When did they have to become licensed? When did that start? 3 As far as -- as long as I've been 4 Α. 5 here. 6 0. Okay. And do they go through the 7 same application and review process and renewal process similar to techs? 8 9 Α. Yes. 10 And when you do your inspections, do 11 you check on the current status of the pharmacy 12 interns and pharmacy techs and pharmacist 13 licenses? 14 Α. Yes. 15 0. And is it important to the board, 16 when you do your inspections, to make sure that 17 everybody and anybody is properly licensed? 18 Α. Yes, that's very important. 19 Are you familiar with the Ohio Ο. 20 regulations concerning the so-called manner of 21 processing prescriptions regulations? 2.2 Α. Yes. And do those regulations set forth 23 Ο. 24 the steps that the board wanted the pharmacists to follow when filling prescriptions? 25

- A. Yeah. I think it's -- I mean, I don't know exactly, you know, why it was implemented, but to me, my interpretation is that it's for pharmacists and prescribers.
- Q. I see. Okay. And are you familiar with the term "patient profiles," pharmacies having patient profile systems under the regulations, that was a requirement?
  - A. Yes.

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- Q. And is that something you look for in your inspections, to make sure that the pharmacy had an ability -- had a patient profile system so that when a prescription was being filled, the pharmacist could access that patient profile and take a look at the prescribing history for that patient at that store?
  - A. Yes.
- Q. Was that an important part of the regulations in your mind?
  - A. Very important.
  - Q. Why was it so important?
- 22 A. For various different reasons.
- It's going to ensure that there aren't any type
- 24 of medical interactions or drug interactions,
- 25 | not just controlled substances but all

medication that's being dispensed to a patient. A pharmacist uses their clinical knowledge and all their additional resources to ensure that the patient is not getting anything that is unsafe for them or is going to have any other interactions with any of the other medications that they are taking. And it also is used to review any potential early -- early fills of controlled substance medication. It could be indicative of any potential addiction issues or suspicious issues that could come up from reviewing that patient profile.

- Q. Okay. But that patient profile system was not an OARRS system, it was a -- it's a store system; is that right?
  - A. Yes.

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Q. And did the Board of Pharmacy ever require a pharmacy location to have any different type of system other than the patient profile system which showed that patient's prescribing history for that store?

MR. WEINBERGER: Objection.

A. No. As far as I -- as far as I'm aware, they have to have a patient profile system that could speak to any other pharmacies

Page 103 that are in there. If it's a chain, they have 1 to be able to review all those prescriptions. 3 If it's just an independent pharmacy, then, you know, it's strictly -- strictly limited to just 4 5 those prescriptions. If you would look at Exhibit 10 in 6 the first binder. 7 Are we talking the volume 1 binder? 8 Α. 9 0. Yes. Are you with me? 10 Α. I'm still searching for it. Okay. 11 You see that's Ohio Regulation 0. It's called "Patient Profiles." 12 4729-5-18. 13 Α. Nope. I'm sorry. I'm at Manner of 14 Processing a Prescription. 15 0. Go to the third page of that 16 exhibit. 17 Α. Okay. 18 Are you with me now? It's at 5-18, "Patient profiles." 19 20 Yes. Α. 21 And do you recognize this as the 22 patient profile regulation for pharmacies? 23 Α. Yes. 24 And does that list the requirements 0. 25 under the Ohio regulations for what a pharmacy's

patient profile system must contain?

Α. Yes.

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- And you see under A there's a listing from A-1 through 1 and 2. The number 1 is the patient's data record containing the full name of the patient, address, telephone number, date of birth, gender, patient specific data consisting of drug-related allergies, previous drug reactions, history of or chronic conditions or disease states, other drugs and nutritional supplements. So is that your understanding that that's what the regulations require to be in the patient's data record?
  - Α. Yes.
- 0. All right. And part (f) of A(1)(f), "Pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug, " that was also a requirement for the patient profile system?
  - Α. Yes.
- Ο. Part 2 of this regulation says, "The patient's drug therapy record, which shall contain at least the following information for all of the prescriptions that were filled at the

pharmacy within the last 12 months, showing name and strength of the drug or device, prescription number, quantity dispensed, date dispensed, name of the prescriber, " and there's directions for use. Does that indicate to you that that's -- that that was the regulatory requirement for the patient profile system?

A. Yes.

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Q. And then, just to complete this regulation, under part B, "Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate unless there is reasonable cause to believe the information is inaccurate," that was also part of the patient profile system, correct?

A. Yes.

Q. And then finally, part C, "The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or a computerized form." So is it your understanding that the patient profile had to go back for one year from the date of the last entry?

Page 106 MR. WEINBERGER: Objection. 1 2. Ο. Go ahead. 3 That's my understanding. Α. And is that the regulation you were 4 Q. 5 enforcing when you went in and did your investigations? 6 7 MR. WEINBERGER: Objection. 8 Α. Generally they have much longer. 9 The patient profiles are -- they go well beyond 10 one year. 11 Okay. Going back to Subsection O. 12 A(2) --13 MR. WEINBERGER: I withdraw the 14 objection to the last question. 15 -- "for all of the prescriptions 16 that were filled at the pharmacy, " is that a 17 reference to the pharmacy that filled the 18 prescription, the specific store? 19 MR. WEINBERGER: Objection. 20 Yes, I believe that's for the Α. specific store; however, like I had indicated 21 22 earlier, if you have a chain, they can 23 generally see medications that were dispensed 24 from other pharmacies within the chain. Okay. But what I'm getting at is to 25 Q.

Page 107 try to understand the regulation. 1 The actual 2. regulation requires a patient profile for the 3 specific store that fills the prescription? MR. WEINBERGER: Objection. 4 5 Α. Yes. Okay. Are you familiar with the 6 0. term "drug utilization review"? 7 8 Α. Yes. 9 What is that in your mind? Ο. 10 In my mind, it's a pharmacist Α. 11 using -- using multiple items to make a 12 determination prior to dispensing the 13 medication, make sure that it's safe and, you know, they're going to use things like review 14 15 the patient profile, review OARRS, review some 16 of their clinical knowledge and even some of 17 their clinical resources to really ensure that the medication is issued for a legitimate 18 19 manner and that it's safe for the patient to 20 consume. 21 When you did your inspections, were 22 you -- were part of your inspections to ensure 23 compliance by the pharmacy with the drug 24 utilization review regulation? 2.5 Α. Yes.

- Q. Okay. If you go back to Exhibit 10, this Edwards Exhibit 10, right after the page we just went over for patient profiles, there's Prospective Drug Utilization Review Regulation 4975-5-20.
  - A. Yes.

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- Q. Do you recognize this regulation as the regulation that you were ensuring compliance with when you went into your inspections?
  - A. Yes.
    - MR. WEINBERGER: Objection.
  - A. Yes, I do.
- Q. Now, this drug utilization review regulation requires -- at the very beginning requires, prior to dispensing any prescription, a pharmacist shall review the patient profile, which is what we just went over. Was that your understanding?
  - A. Yes.
- Q. And there's a list here of things
  that -- it's for the purposes of identifying
  things like over-utilization or
  under-utilization, therapeutic duplication, drug
  disease state contraindications, drug-drug
  interactions, incorrect drug dosage, drug

allergy interactions, abuse, misuse, inappropriate duration of drug treatment, and food-nutritional supplement drug interactions. Is that your understanding of the regulatory requirement for drug utilization reviews?

- A. Yes, to my understanding.
- Q. Okay. Now, part B of this regulation states that upon identifying any issue listed in that list we just went over, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problems. These steps may include requesting and reviewing an OARRS report or another state's report pursuant to paragraph D of this rule and/or consulting with the prescriber and/or counseling the patient.

Did you -- were you aware of this regulation as part of the drug utilization review process?

A. Yes.

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- Q. And what did you understand the reference to a pharmacist using professional judgment to mean?
- A. And this is my interpretation of it, but they -- they rely on all their

Page 110 resources, all their clinical knowledge, all 1 2. their education, and, you know, using their 3 professional judgment to potentially not fill the prescription, if that's need be, or contact 4 5 the physician, maybe, you know, have some sort of different strength or something of that 6 nature, but that's kind of -- to me that's how I interpret a pharmacist using their 8 9 professional judgment. 10 MR. WEINBERGER: Objection. Move 11 to strike. 12 Now, did the board ever require 0. 1.3 pharmacists to do anything specific in terms of exercising their professional judgment in that 14 15 regard? In other words, to your knowledge, is 16 there any regulation or requirement by the board 17 that a pharmacist follow specific steps in every 18 instance in filling a prescription? 19 MR. WEINBERGER: Objection. 20 Could you -- could you ask that Α. 21 question again? I'm sorry. 2.2 Ο. Sure. 23 We just read this Subsection B of 24 the drug utilization review regulation and it

references professional judgment, and it says,

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"These steps may include requesting and reviewing an OARRS report or another state's report and/or consulting with the prescriber and/or counseling the patient." My question is, do you review these -- or do you view these regulatory requirements as a mandatory requirement that in every instance a pharmacist is required to request an OARRS report or consult with the prescriber or counsel the patient or, instead, is that a matter of professional judgment?

MR. WEINBERGER: Objection.

- A. My interpretation is it's a matter of professional judgment.
- Q. Okay. Now, Subsection D of this regulation references the OARRS -- the conditions under which OARRS has to be consulted. Are you familiar with this section of the regulation?
  - A. Yes.

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Q. And when you did your inspections, did you take a look at, from time to time, compliance with this regulation, making sure that pharmacists were consulting OARRS when required to from time to time?

MR. WEINBERGER: Objection.

A. Yes.

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- Q. And what is your understanding of when a pharmacist, under this regulation, was required to consult OARRS as opposed to do it discretionary under the professional judgment standard?
- Well, at the very bare minimum, as Α. long as nothing has changed with the patient's prescriptions, OARRS should be reviewed every 12 months. Anytime a new controlled substance is introduced into their drug therapy, a new physician prescribes a controlled substances -a controlled substance, then they should review OARRS. If there's any red flags, such as the patient comes in with a prescription from a prescriber outside of the geographical area or the patient is outside of the geographical area, they should be reviewing OARRS. And, in general, if they have any type of suspicion of addiction or impairment or overusage of their medication, then the pharmacist should be accessing OARRS.
- Q. All right. Well, let's look at the regulation, part D(1), and the precursor of part

D says in any of the following circumstances, review the OARRS report. The first one says, "A patient adds a different or new reported drug to their therapy that was not previously included." So you mentioned that a second ago, but if it's a new drug, check OARRS?

A. Yes.

- Q. Number 2 says, "An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile," so, in that instance, which you also mentioned, check OARRS?
  - A. Yes.
- Q. Number 3 says, "A prescriber is located outside the usual pharmacy geographic area," and, in that instance, check OARRS, right?
  - A. Yes.
- Q. What do you understand the term to be "outside the usual pharmacy geographic area"? Is that a specific mileage requirement or does it depend on the facts and circumstances of the pharmacy?
- A. It depends on the specific facts and circumstances of the pharmacy.

- Q. To your knowledge, did the board at any time ever tell the pharmacies that you better check OARRS if it's X number of miles, if the prescriber is X number of miles away from the pharmacy?
- A. No. That's never been communicated.
  - Q. So who makes this determination of whether they need to check OARRS because of being outside the usual pharmacy geographic area?
    - A. The pharmacist does.
    - Q. It's up to the pharmacist?
- 14 A. Yes.

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- Q. What about number 4, "A patient is from outside the pharmacy geographic area"? Is that, similarly, a matter of the pharmacist's professional judgment?
- 19 A. Yes.
  - Q. And, similarly, did the board ever advise the pharmacies that if a patient is X number of miles away from the pharmacy, you have to check OARRS?
- A. No. That's -- as far as I'm aware,
  that's never been communicated.

Q. Okay. Number 5 says, "A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding three months unless the prescriptions are from prescribers who practice at the same physical location."

So how would a pharmacist have reason to believe this, that a prescription has been received from more than one prescriber in the preceding 3 months?

- A. Probably from reviewing the patient profile, and then also they would confirm it or deny it through OARRS.
- Q. Well, this is a checklist of when to check OARRS, so this would be the trigger for checking OARRS, and so what I'm getting at is, before they check OARRS, this is saying check OARRS if the pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months. So when, in your experience, would that trigger the need to go check OARRS? I'm not talking about what he would see when he got into OARRS. I'm saying how does that work, how does that trigger?

- A. So my -- my guess would be that's coming from reviewing the patient profile.
- Q. Okay. And then, finally, the regulation has a section 6 under this list of when to check OARRS, "Patient is exhibiting signs of potential abuse or diversion." What does that mean?
- A. That could be a multiple -multitude of things. It could be a patient
  that comes into the pharmacy impaired. It
  could be a patient that, you know, repeatedly
  asks for early refills of their medication.
  They may -- a pharmacy may have been notified
  by someone that this person is abusing their
  medication or selling their medication or
  something of that nature.
- Q. Is this a subjective thing that the pharmacy looks for in its professional judgment?
  - A. Yes.

Q. And it says, "This includes, but is not limited to, overutilization, early refills," which you just mentioned, "appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting reported drug by

Page 117 specific names, street name, color or 1 2. identifying marks." 3 Again, this is something that would come up in the patient profile or on this 4 5 objective observation of the pharmacist? This would be a -- I think some of 6 7 it could come up in a patient profile, such as those early refills. I think generally 8 9 pharmacists -- if this is a once in a --10 something that's never been requested and 11 there's a legitimate explanation, they may 12 dispense an early refill a few days; however, 13 some of these other things, such as exhibiting 14 signs, those are purely -- those are purely 15 observations that would be made by the 16 pharmacist. 17 Ο. Okay. Now, Agent DiFrangia, you 18 mentioned a couple minutes ago a concept of red 19 flags. By that term did you mean these items we 20 just went over in the drug utilization review, 21 Subsection D? 2.2 Α. Yes. 23 MR. APPEL: Bob, this is Henry 24 I'm just letting you know that it's Appel. 25 approaching 11:30.

MR. BARNES: Okay. What time do we have, 11:28? Let me see if we can finish this regulation.

- Q. The last portion of this regulation, Subsection G, do you see that?
  - A. Yes.

- Q. "A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his or her professional judgment." Did you look to see compliance with this portion of the regulation when you did your inspections?
- A. I mean, we would generally ask pharmacists, but, you know, this is something that you can't -- you can't visually see as an inspector.
- Q. But you did look at dispensing records from time to time to ensure compliance with the regulations?
- A. Yeah. We would look at dispensing records, we would ensure that they're running OAARS, we would ensure that they're conducting a drug utilization review and that they're not relying solely on the dispensing software. So, yeah, I mean, I guess -- I guess if you take

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all those things combined, then we are checking to ensure, you know, that prescriptions are being issued for a legitimate medical purpose based on those things; however, you know, are there specific things that we just don't know -- I mean, we ask the pharmacists sometimes about prescribers, if there's any suspicion of questionable prescribing with anyone. You know, unless they tell us, we generally don't know that sometimes.

Q. All right. One last question before we break.

Going back to Subsection D of the regulations and this concept of the red flags, other than these red flags in subsection D of this regulation, are you familiar -- are you aware of the Board of Pharmacy ever advising pharmacies or pharmacists that there were any other red flags that they needed to look out for in terms of regulations?

MR. WEINBERGER: Objection.

A. I'm sure there's other red flags that we have, you know, advised them of through guidance documents, but, you know, nothing -- nothing exactly comes to mind, but it's not

Page 120 limited just to these items in here. 1 2. 0. Okay. What other red flags are you aware of besides what's listed here? 3 Well, like I said, you know, if 4 Α. 5 they get any information of someone that is, you know, potentially abusing their medication 6 7 or diverting it or selling it, you know --Okay. So if they have specific 8 0. information that somebody may be a bad actor, 9 10 they should consider that? 11 Yeah, or, you know, sometimes 12 you'll get a carload of individuals where four 13 of them are presenting similar prescriptions from a prescriber. You know, again, that's --14 15 that's a pretty suspicious scenario that I 16 think most reasonable pharmacists would 17 exercise their professional judgment and not dispense that medication. 18 19 MR. BARNES: Okay. We agreed to 20 break at 11:30 so Henry could take care of some matters. We'll take a lunch break and be back 21 22 at 12:30. 23 THE VIDEOGRAPHER: We are going off 24 at 11:32. 2.5 (Luncheon recess had.)

Page 121 1 THE VIDEOGRAPHER: We are back on 2. the video record at 12:33. 3 AFTERNOON SESSION 4 5 CONTINUED EXAMINATION OF WILLIAM DIFRANGIA 6 BY MR. BARNES: 7 Good afternoon, Agent DiFrangia. 0. We're back on the record after a lunch break. 8 9 We were looking at Edwards Exhibit 10 10 and I want to pick up there, just a few 11 questions. These are the regulations related 12 to how prescriptions are to be filled, 13 including 4729-5-20, 21, 18, 16, 22 and 09. We 14 were talking about the drug utilization review 15 regulation, 5-20. 16 Α. Okay. 17 Do you remember that? We walked through that. 18 19 Α. Yes. 20 And we were talking about Subsection Q. 21 G, which begins, "A prescription, to be valid, 22 must be issued for a legitimate medical purpose by an individual prescriber acting in the usual 23 24 course of his or her professional practice." 25 Do you see that?

A. Yes.

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- Q. Now, the reference to "a legitimate medical purpose," in your experience, can you determine if a prescription is valid without talking to or looking at the records of the doctors?
- A. You know, I don't -- I don't know that I can answer that because I don't -- I'm not a pharmacist and I don't have the -- you know, I don't have the background or education or practice of a pharmacist.
- Q. But when you were doing your investigations of doctors -- and we've covered a few of those -- would you look at the doctor's records if you were -- if you suspected bad prescriptions?
- A. Yes. Ultimately we would generally get patient records and review them or we would have an expert physician review them.
- Q. Okay. Because you weren't medically trained but you needed the input of a medical -- medically trained professional?
  - A. Correct.
- Q. Now, the second sentence of this regulation says -- begins, "The responsibility

Page 123 for the proper prescribing is upon the 1 2. prescriber." How did you understand that portion of the regulation? 3 Well, my interpretation -- and I'm 4 5 not a lawyer or an attorney. My interpretation is just that, you know, it rests -- it's 6 7 upon -- the responsibility is upon the prescriber that's issuing the prescription, but 8 9 that's just my interpretation of it. 10 Okay. Does -- was that the 11 understanding you had and have had while you 12 have been functioning as an agent for the board? 13 Α. Yes. 14 MR. WEINBERGER: Excuse me for just 15 a second. I was on mute. With respect to the 16 prior answer, would you please note an 17 objection and motion to strike? Thank you. 18 MR. BARNES: Pete, are you asking 19 her to read something back? 20 MR. WEINBERGER: No. No. I just 21 wanted her to note on the record an objection 22 and that I was moving to strike the answer to 23 the question prior to that question and answer 24 because I was on mute. 2.5 THE COURT REPORTER: Yes, I will

Page 124 1 note that. 2. MR. WEINBERGER: Thank you. 3 Continuing in that regulation, Agent Q. DiFrangia, it says -- after the responsibility 4 5 for proper prescribing being on the prescriber, it continues that a corresponding responsibility 6 rests with the pharmacist who dispenses the prescription. 8 9 Do you see that? 10 Α. Yes. 11 And you've referenced this 0. 12 corresponding responsibility in the past, in 13 your past testimony, but continuing with this regulation, it says, "Based upon information 14 15 obtained during a prospective drug utilization 16 review, a pharmacist shall use professional 17 judgment when making a determination about the 18 legitimacy of a prescription." 19 Is that how you understood it, that 20 the corresponding responsibility after the prescriber's responsibility for the 21 2.2 prescription at the beginning, the 23 corresponding responsibility is based upon the 24 drug utilization review? 2.5 Yes, that's my understanding. Α.

Q. And the professional judgment aspect, how did you understand that to operate?

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A. Well, it would be within a pharmacist's professional judgment to dispense medication or not or potentially adjust the medication through contacting the physician. That's the way I would interpret that.

Q. Okay. And this regulation finishes by saying, "A pharmacist is not required to dispense a prescription of doubtful, questionable or suspicious origin."

How did you understand that portion of the regulation?

- A. Just frankly pretty much as it says, that they don't have to dispense medications if they feel, you know, for any different reason that it's not warranted.
- Q. All right. Did you understand that the professional judgment of a pharmacist, when dispensing, could include things like prior relationships with the patients, knowledge of the doctors, things of that nature?
- A. I'm sure that can all come into their decision-making.
  - Q. Okay. Now, when we get back to this

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- 1 5-21, Manner of Processing a Prescription
- 2 Regulation, which is in Edwards Exhibit 10,
- 3 | you'll see in part B -- it's the first page of
- 4 Exhibit 10 -- part B says, "A pharmacist when
- 5 dispensing a prescription must, " and then it
- 6 lists five steps, ensure that patient
- 7 information is profiled pursuant to 5-18 of the
- 8 | code. We went over that, right?
- 9 A. Right.
- 10 Q. Step 2 is perform prospective drug
- 11 utilization review pursuant to 4729-5-20, and we
- 12 | went over that; is that right?
- 13 A. Yes.
- 14 Q. And then the third step is ensure
- 15 that the drug is labeled pursuant to 4729-5-16.
- 16 Are you familiar with that labeling requirement,
- 17 and if so, what was your understanding of it?
- 18 A. Yes, I am familiar with it. My
- 19 understanding is that it -- there's specific
- 20 | items that are required to be on a prescription
- 21 | label, such as the patient's name, address,
- 22 medication, strength, quantity of the
- 23 | medication, direction for use, the prescriber
- 24 of the medication, and instructions for when to
- 25 take that medication.

- Q. That regulation, 5-16, is several pages into Edwards Exhibit 10. Does that help you refresh your recollection as to what the labeling requirement was? Do you see that, 4729-5-16?
- A. Yes.

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- Q. Are those listed there under A(1) through (10)?
  - A. Yes.
- Q. And when you did your inspections, were you in part making sure that the pharmacies complied with this regulation?
  - A. Yes.
- Q. So going back to the 5-21, Manner of Processing regulation, the fourth step is "Ensure that the patient is given an offer to consult pursuant to Rule 4729-5-22." Were you familiar with that regulation, and if so, what was your understanding?
- A. Yes, I am familiar with it, and again, my interpretation just coming from me -- I'm not a lawyer -- the interpretation is that each prescription that is dispensed and offered to provide consultation is required by the pharmacist to the patient.

- Q. And is that something that you've checked on when doing your inspections, compliance with this patient counseling regulation?
  - A. Yes.

- Q. And would that include looking for things like counseling logbooks, where patients would sign off that they did or didn't want counseling?
- A. Yes. There would be a counseling log where the pharmacist would document who -- which pharmacist provided the counseling, and then there's also usually documentation where the patient declines it if they do not want any counseling.
- Q. Okay. And do you recognize this regulation in Edwards Exhibit 10, 4729-5-22?
  - A. Yes.
- Q. And then going back to the 5-21, Manner of Processing, after the labeling and counseling, the last step, number 5, is "Ensure that a prescription is filed pursuant to 4729-5-09." And that's also in Exhibit 10. It's the last page. But how did you understand that regulation and were you aware of it?

- A. Yes, I was aware of it. My understanding of it, just my interpretation -- this is not -- again, I'm not a lawyer -- my interpretation is that hard copy prescriptions have to be maintained in a prescription file and they have to be separated by way of schedule, Schedule II and then III through V, and then all non-controlled prescriptions.
- Q. Okay. Again, when you did your inspections, were you looking for compliance with that regulation?
  - A. Yes.

- Q. So going back to the 5-21, Manner of Processing a Prescription, under B(1) through (5), are those the five steps that Ohio law required pharmacists to follow when filling a prescription?
- A. Yes, that's the way I interpret that.
- MR. WEINBERGER: Objection. Move to strike.
  - Q. I want to focus your attention,
    Agent DiFrangia, on inspections. We talked at
    length already about inspections, but there are
    regulations, Ohio regulations, governing

Page 130 inspections, correct? 1 2. Α. Yes. 3 0. And if you look at Edwards Exhibit 11 --4 5 Α. I have it. -- do you recognize these as the 6 0. 7 Ohio regulations governing inspections of pharmacies? 8 9 Α. Yes. 10 And do these regulations provide the 11 Board of Pharmacy and its agents and inspectors 12 the right to inspect a pharmacy upon application 13 for a license and at any time thereafter? 14 Α. Yes. 15 Q. Do you recognize Edwards Exhibit 12? 16 Yes, I do. Α. 17 What is it? Q. 18 So this is an inspection guide that Α. 19 this -- this is put on our website and it's 20 available for -- for review. Pharmacists, 21 pharmacies, they can review it and kind of get 2.2 an idea of what our expectations are during 23 inspections. 24 Ο. And it's relatively new. It looks like it was dated December 1 of 2020. Is that 2.5

Page 131 right, it just came out very recently? 1 2. Α. Yes. 3 Is this the first inspection guide that you're aware of that's been used by agents 4 5 or inspectors of the board? No. We've had some informal things 6 7 that we would use as guidance while conducting inspections, but this is the first to be put on 8 9 our website. 10 O. I see. And so is it -- my 11 understanding correct that this isn't 12 necessarily new things that are new standards 13 for inspections, but instead, this is the first 14 time they've been compiled and put on the 15 website? 16 Well, these -- a lot of these are 17 new rules, and I think because of so many 18 changes, my guess is that maybe that's why it 19 was put on the website. 20 And have you used this guide in your Q. inspections? 21 2.2 Α. You know, I -- I don't think I 23 have, primarily because since the pandemic has 24 taken place, we really have been limited to our exposure in pharmacies. 25

Q. There are sections of this inspection manual -- for example, on page 33 there's a reference to dispensing records and patient profiles.

Do you see that?

A. Yes.

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- Q. And the question appears to be,
  "Does the pharmacy maintain dispensing records
  containing the required information?" And it
  lists a lot of -- a lot of requirements. My
  question to you is, regardless of whether or not
  this manual came out recently, but are these the
  types of things that you covered in your
  inspections before this manual came out to make
  sure that pharmacies that you inspected were
  maintaining adequate dispensing records?

  MR. WEINBERGER: Objection.
- A. Yeah, for the most part. These -these are pretty much the items that we have
  reviewed even prior to the issuance of this
  during inspections.
- Q. All right. So part of your inspections included review of the pharmacy's dispensing records?
  - A. Yes.

- Q. Okay. And then part of your inspection, did it also include making sure that the pharmacies were keeping the records for the required regulatory time frame?
  - A. Yes.

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- Q. And in that regard, if you look at page 39 of this inspection manual, this is geared towards general recordkeeping requirements. What did you understand to be pharmacies' recordkeeping requirements in terms of time frame? How long did they have to have records; one year, two year, three years? That's what I'm getting at.
- A. They're required to keep three years' worth of records.
- Q. Okay. And is that something you looked for in your inspections, to make sure they were complying with that three-year recordkeeping requirement?
  - A. Yes.
- Q. Page 43 of this inspection manual governs security, control and storage of dangerous drugs. Was that part of your inspections before this manual came out, to review security controls and storage of

Page 134 1 dangerous drugs? Α. 2. Yes. 3 Page 56 of this manual deals with prescription formatting and manner of issuance. 4 5 We just went over the manner of issuance requirements, but before this manual came out, 6 7 did you, in your inspections, follow substantially the same or similar procedures as 8 9 indicated under this section, and that begins 10 with do outpatient prescriptions comply with the 11 manner of issuance rule that we just went over, 12 4729-5-15? 13 Α. Yes. 14 0. Do you see that? 15 Α. Yes. 16 Now, you are familiar with the Q. 17 inventory requirements for pharmacies, correct? 18 Α. Yes. 19 And is that something that you 20 looked for compliance with in your inspections, 21 to make sure that they were taking an adequate 2.2 number of controlled substance inventories? 23 Α. Yes. 24 And is Edwards Exhibit 13 the Ο. 25 regulation that you were enforcing during those

Page 135 inspections? 1 2. Α. Okay. 3 Are you familiar with this 0. regulation, 4729:5-3-07? 4 5 Α. Yes. All right. And what did this 6 0. 7 regulation require for pharmacies in terms of 8 conducting inventories of their controlled substances? 10 Α. Well, again, my interpretation only 11 is that, you know, they were required annually 12 to take an inventory of all their controlled 13 substances, and they also had to do so when 14 they change responsible persons within the 15 pharmacy. 16 MR. WEINBERGER: Move to strike. 17 So that was an annual inventory Q. 18 requirement. In your inspections did you see 19 from time to time pharmacies doing those 20 inventories more frequently than the regulatory 21 once-a-year requirement? 2.2 Α. Yeah, from time to time. 23 Okay. Do you recall specifically, 0. 24 for example, Giant Eagle conducting these 2.5 inventories more frequently than annually?

- A. No, I don't, not for the controlled substance inventory.
  - O. You don't recall that?
- A. Not off -- no, not off the top of my head.
  - Q. Okay. Fair enough. I probably wouldn't remember either. But if they did -MR. WEINBERGER: Objection. Move to strike the comment.
  - Q. Do you view having more frequent controlled substance inventory as a good internal control?
    - A. Yes.

Α.

Okay.

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Q. Now, Agent DiFrangia, we've compiled -- the board was kind enough to produce inspection reports for the pharmacy Defendants, and Exhibit -- Edwards Exhibit 16 were the ones conducted by Trey Edwards -- I'm sorry, Exhibit 15 for Trey Edwards, Exhibit 16 were those conducted by George Pavlich, and Exhibit 17 were all other inspections in these two counties, Lake and Trumbull, conducted by other inspectors, including yourself. So if you can look at Edwards Exhibit 17.

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- Q. Do you recognize these documents as inspection reports prepared by Board of Pharmacy agents?
  - A. Yes.

- Q. Do you recognize any of the names, Mr. Bodi, for example, on the first page?
  - A. Yes.
- Q. Did the agents at the board, including yourself, work together with respect to the inspections that they were doing? In other words, would you cross-check against the other agents to see -- you know, if you were going out to inspect, for example, a Giant Eagle pharmacy, you told me earlier you would check prior inspection reports. Would you also talk with agents who had done those inspections to see if there was anything notable about their inspections?
  - A. Yes.
- Q. Okay. Do you recall talking with any of your fellow agents about Giant Eagle pharmacies?
- A. I mean, I'm sure I've had conversations with fellow agents about Giant Eagle pharmacies, but nothing, you know,

Page 138 specific that I can really think of. 1 2. Ο. Okay. In this Exhibit 17 I was able 3 to locate approximately four or five inspection reports, and if you look at -- I don't know how 4 5 many pages it is, but it's probably 30 or so 6 pages -- there's an inspection beginning on 7 BOP\_MDL-2799241. 8 Do you see that? 9 Α. 2799241? 10 Yes. Ο. 11 And this is an inspection that you 12 prepared. Is that your signature? 13 Α. No, that is not mine. 14 Oh, it's not yours? Ο. 15 Α. No. 16 Do you recognize it? Whose is it? Ο. 17 No, I -- I don't recognize that Α. signature, and I'm looking at a date that's 18 19 next to it of July 23, 2012. 20 Good catch. Okay. I was misreading Q. 21 signatures. I thought maybe you had done that 22 I'm not going to ask any questions about 23 that since you didn't prepare it. 24 Continue on back in that exhibit -go to MDL2796514. Are you with me? 2.5

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Page 139
1
                 MR. APPEL: I'm sorry. Which
2
    exhibit are we looking at?
3
                 MR. BARNES: We're looking at
    BOP_MDL2796514. It's an inspection dated May
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5
    23rd of 2017, Giant Eagle pharmacy in Warren,
6
    Ohio.
7
                 MR. APPEL: I'm sorry. But which
    exhibit packet is it in?
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                 MR. BARNES: It's 17, Edwards 17.
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                 Probably from about 15 pages from
           0.
11
    the back, Agent DiFrangia.
12
           Α.
                 Yeah, I'm still searching.
13
           Ο.
                 Unfortunately, these aren't in
14
    sequential numbers.
15
           Α.
                 Okay, I have it.
16
                 This is an inspection that you
           Ο.
17
    performed. Your name is on the second page, 2
18
    of 4, Agent William DiFrangia.
19
           Α.
                 Yes.
20
                 Did you prepare this document?
           Q.
21
           Α.
                 Yes.
22
           Ο.
                 All right. And you prepared this
    document to record the results of your
23
24
    inspection of Giant Eagle pharmacy 1419 on 2061
    Elm Road, Warren, Ohio?
25
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Page 140 1 Α. Yes. 2. Ο. It says this is a category 3 barricade inspection. I think you told me 3 already what a barricade inspection was. 4 5 Α. Yes. The second page of this exhibit 6 0. 7 references the personnel Barbara Susan Carlson, pharmacist, and Kellie Cleland, pharmacist? 8 9 Α. Yes. 10 Did you interact with either of 11 those pharmacists during this inspection? 12 I believe I interacted with Barbara 13 Carlson. I'm not sure about Kellie Cleland. 14 Okay. And does this -- does this Ο. barricade inspection document the results of 15 16 your inspection? 17 Α. Yes. Was Pharmacist Carlson cooperative 18 Ο. 19 with you? 20 Α. Yeah. As far as I can remember, if 21 she was there, she was. 2.2 Ο. Okay. Do you have any other recollections about either of these pharmacists 23 in terms of having worked with them for any 24 25 reason in the past?

- A. Yeah. I think I had requested records from both of them in the past.
- Q. And did they provide those records and cooperate with you?
- A. Yes.

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- Q. And the results of this inspection at the end are no issues found; is that right?
  - A. Correct.
- Q. So when you did an inspection and wrote it up in these reports, if there was an issue found, you would document it, correct?
  - A. Yes.
- Q. I like the new inspection reports,
  by the way. You don't have to decipher
  handwriting.
- 16 A. Right.
- Q. If you go about six pages later -
  I'm looking for the next inspection report that

  you did. It begins on -- six or eight pages

  later -- BOP\_MDL2796530.
  - A. What date are you looking at? Sometimes that will be easier to spot it.
- Q. Sure. December 18th of 2018, first page.
- 25 A. Okay. Yes, December 18th, 2018.

- Q. And is this another inspection report showing the results of an inspection of Giant Eagle pharmacy 1419, 2061 Elm Road, Warren, Ohio, Trumbull County?
  - A. Yes.

- Q. Now, this says, "Retail Pharmacy
  Inspection" whereas the last one called it a
  barricade inspection. So is this a more normal
  type inspection being conducted here?
- A. Yes. This is more of a -- more inclusive inspection. The other one was just specifically geared around the barricade because I think we had mentioned that they had an attempted break-in to the pharmacy.
- Q. Got it. So on page 2 of this inspection it shows, again, Pharmacist Carlson and now another pharmacist, Nicole Deluco, as well as several technicians. When you list these individuals, are these individuals that were there during your inspection?
- A. For the most part. The way the inspection guide is -- whoever the responsible person is or pharmacy manager, their name is always on there, whether they're present or not, so I -- out of the pharmacists, one of two

was definitely present, maybe both of them, but it like auto populates within the inspector, the inspection software.

Q. Okay. And this now seems to be a more in-depth listing of multiple things that you looked for in this inspection, beginning with the licensing requirement, number 1, which we've talked about.

Do you see that?

A. Yes.

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- Q. And then you continued -- you look at the responsible person issue. In fact, here you noted that there was a change in responsible person reporting to the board and you noted it in your inspection report, correct?
  - A. Yes.
- Q. And then you looked at the DEA certificate again, looking to make sure that they were all currently licensed; is that right?
  - A. Yes.
- Q. In 2.1 you looked at record availability. "Can the pharmacy produce a detailed patient profile for the last 12 months immediately upon request?" And you said "Yes" and then you made an observation. Am I correct

that this is one indication of what you told me earlier, that you were enforcing the patient profile regulation that we went over?

- A. Well, yes and no. The observations that I put in there is something kind of different. It was related to something different, but that's in a way how we -- I was able to ensure that that's being complied with.
- Q. Okay. The next section, 2.3.1, is relating to dispensing software, and you made an observation of EPS. Why did you care about dispensing software?
- A. Well, we want to know who makes the software, who -- you know, is it a Giant Eagle system that they own or is it a third-party vendor. There are times when maybe if a pharmacist or someone with access is diverting medication, they may have different levels of access than other people, and, you know, these things can be -- it could be helpful in further investigations to know what the software is that they're using.
- Q. And was -- your observation was that Giant Eagle was using EPS. Was that an acceptable and satisfactory software --

dispensing software system as far as the board was concerned?

A. Yes.

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- Q. On the next page, 2.3.4, "Shared Dispensing Software: Is there a real time online system and used for the review and transfer of dispensing data? Yes. Observation? Yes." Why did the board care whether it was a real time online system?
- A. Well, I think for the purposes of, you know, we want to be able to ensure proper drug utilization review is being conducted, and if someone goes to one Giant Eagle, you want to know that, you know, if they went to another one, this way the same pharmacy at a different location isn't dispensing the same medication to someone.
- Q. So having a real time online system, as indicated here, is a good internal control from the board's perspective?
  - A. Yes.
- Q. Okay. In fact, it says here, "Does the pharmacy's real time online system prevent a patient from receiving more dispensings than authorized by the original prescription?" And

you said, "Yes." So that's actually a control built into the system that prevents diversion?

- A. I can't say for sure if it's built into the system or exactly how the system works, but, you know, they -- it would be something that -- how it would alert them, I'm not exactly sure, but it does -- you know, they are able to see that information.
- Q. Okay. And then you continue, 2.3.6, "Dispensing Record Accuracy. Are required records of accountability being kept complete and accurate in the dispensing software?" And you said "Yes" here. Is that something the board wanted to make sure pharmacies were doing, keeping accurate dispensing records that could be reviewed when necessary?
  - A. Yes.

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- Q. Now, 2.5 deals with ePositive identification, and it references a paperless positive ID system being used and whether it was approved by the board. What is an ePositive identification system?
- A. Well, pharmacists are required to provide a positive identification for essentially every step of the dispensing

process, and generally the way that's captured is with a -- with a wet ink signature or initials, just a pharmacist writing her initials, dating a prescription. So some -- some pharmacy chains -- Giant Eagle is one of them -- they have adopted an ePositive ID system, where they do not use a wet ink signature on the prescription, it's done -- it's captured electronically, the positive ID is. So that was approved, that had prior board approval and that was -- that was done on February 20th of 2015 at this Giant Eagle in Elyria, and that shows as approval statewide for their system.

- Q. I see. And is that a good control from the board's perspective, to have this ePositive identification system?
  - A. Yes.
- Q. And then your report continues through various other areas dealing with the physical and electronic barricades. Part 4 deals with the minimum standards on page 6 of 10. If you look at 4, number 7, "Is there evidence to indicate a problem with staffing levels?" And you had indicated in this

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inspection "No." What was the board's concern in this area as part of its inspections? What was it looking at?

- A. Well, I think if there is -- my interpretation is that if there's -- if there's some sort of staffing issue that is going to affect patient safety.
- Q. I see. So during your inspections you would check into that, as indicated here?
- A. Yeah, just based on my own observations at the pharmacy.
- Q. Okay. Section 5 of your inspection indicates "Security." Number 1, "Is the security of the pharmacy drug stock adequate to detect and deter drug theft and diversion?" And you indicated, "Yes." Can you describe for us what this is all about?
- A. Yeah. It's to ensure that they have some processes in place; that if someone does happen to divert medication or divert records, that they can -- they can deter it, and then if it does happen, that they can detect it. So, you know, some of their systems that they have in place, you know, maybe they do some additional counts of medication or

2.

- something of that nature. Those are things that -- you know, are going to deter and detect the theft of medication and records also.
- Q. We talked earlier in your deposition about the security requirement regulation. Is this part of your inspection a part of that, determining compliance with the overall security regulation?
  - A. Yes.

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- Q. Your reports -- this report continues with a review of the library, cleanliness, refrigeration, drug ordering procedures. Are you following me?
  - A. Yes.
- Q. And then 9.3 references "Electronic Control II drug order receipt. When using an electronic drug ordering system, is the pharmacy creating a receipt that is electronically linked to the original order?" And you said "yes" for this inspection. What is this all about? What are you -- what is this part of the inspection geared towards?
- A. Well, my interpretation is that there is a receipt for any -- they order their drugs, their Schedule II drugs, electronically.

They have to have a receipt of that and it has to, you know, be electronically linked with the order and -- the receipt of those drugs have to be electronically linked.

- Q. Is that an internal control that the board wanted to make sure that the pharmacy was complying with?
  - A. Yes.

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- Q. Now, you list in 9.4 wholesale information, who was the wholesale drug distributor utilized by this pharmacy, and it says here "Cardinal." Why was that part of your inspection? Why did the board care about who the distributor is?
- A. Again, this is my -- this is my own interpretation, is that, you know, at some point other investigations are going to come up with Giant Eagle and, you know, we want to know who's supplying them. Maybe there's an issue with the wholesaler. Maybe in the event we have to do an audit, like we had discussed earlier, you have to know who the wholesale -- who the wholesaler is to conduct that audit. Really it's just my guess, my interpretation is that it could be needed for something in the

future and the information to have is good.

- Q. Are you familiar with the drug distributor Cardinal at the time -- at the time you wrote this report did you know who Cardinal was?
  - A. Yes.

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- Q. Paragraph 10 of your report references improper dispensing -- dispensings.

  "Is there evidence to indicate that a prescription has been dispensed improperly?"

  And the answer here was "No." What does this mean with respect to your inspection? Why were you looking at improper -- potential improper dispensing and whether or not the pharmacy was dispensing properly or improperly?
- A. Well, I think, you know, really you want to ensure that if a prescription has two refills on it, two refills are given. Just an example, you know, two refills are given, not more, not less. If a prescription calls for 20 tablets of some sort of medication, you want to ensure that all that is being done, all the medicine is being done accurately pursuant to the way the prescription is presented.
  - Q. I see. So when you did your

inspections, you actually looked at this area of potential improper dispensing and would indicate whether the pharmacy was complying or not complying; is that correct?

A. Yes.

- Q. And here there was no evidence that this pharmacy had been dispensing improperly; is that correct? Am I reading your inspection report correct?
  - A. Correct.
- Q. Part 11 of your report deals with insufficient supervision. There's two sub-parts. "Is there pharmacist supervision of the dangerous drugs and other pharmacy employees at all times while the pharmacy is open and operating?" You had indicated here "No." What does that mean? Am I reading this as a negative or what did you mean here?
- A. Well, from reading it, it seems -it was probably answered incorrectly by myself
  because I'm just guessing that if there was an
  issue with pharmacist supervision of the
  dangerous drugs, you know, we wouldn't have
  just -- I wouldn't have just told them -- you
  know, wouldn't have just indicated no on the

inspection guide. There would be some sort of corrective action.

- Q. When you fill out these reports, are these inspection reports -- are they online and you go through a checklist and fill it out electronically?
  - A. Yes.

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- Q. Okay. But why even inquire about this area, insufficient supervision? Why does the board care about pharmacist supervision and whether or not only pharmacists are performing tasks requiring professional judgment?
- A. Well, you know, again, my interpretation is that, you know, legally you cannot have a non-pharmacist practicing as a pharmacist, so, you know, we can't allow a pharmacy technician to review a patient profile and do a drug utilization review because they don't have any of the -- any of the education and the background to do so. So I think that's probably -- that's probably the importance of that. And same thing with supervision similar to one of the earlier points of the inspection that we discussed where, you know, proper supervision is going to address things like an

employee that may be potentially diverting drugs or ensuring that, you know, prescriptions are dispensed accurately and all those things are being completed, such as like the drug utilization review.

- Q. Okay. So for this inspection, setting aside the -- what you believe to be an incorrect answer to 1, is my understanding that in this inspection you found that this Giant Eagle pharmacy was properly supervising as required?
  - A. Yes.

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- Q. Okay. You also look in Section 12 at inventory records. During your inspections do you ask the pharmacist for their inventory records to make sure they're complying with the inventory requirements that we went over?
  - A. Yes.
- Q. And here it was okay because you answered "Yes"?
  - A. Yes.
  - Q. 14 and 15 deal with illegal sales and illegal purchases. As part of your inspections were you making sure that the pharmacy was only purchasing from licensed

distributors and wholesalers and that they were handling returned stock correctly?

A. Yes.

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- Q. And here there was no problem; is that correct?
  - A. That's correct.
- Q. In 17.1 you actually look at their drug utilization review software. Is that right? Is that the purpose of this part of the inspections?
  - A. Yes.
- Q. And as part of that, you review whether the pharmacists rely solely on the dispensing software to perform the DUR for prescription dispensing. Here you said "No." What is the nature of this inquiry? What is the board concerned about?
- A. This is you -- what you don't want, you don't want a pharmacist that is merely relying on only the software to conduct a drug utilization review. It's part of it. It's an aspect of it. However, you want them to also include their -- their clinical knowledge, some of their clinical resources and their training and their experience in conducting a drug

utilization review.

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- Q. So here am I reading this right you were satisfied that the pharmacists weren't only relying upon the dispensing software, and, in fact, you observed pharmacists use clinical knowledge in addition to software?
  - A. Yes, that's correct.
- Q. Your inspection report continues,
  Section 19, Improper Prescriptions: "Are the
  prescriptions on file written in compliance with
  4729-5-30?" You indicated "Yes" here. You were
  enforcing that portion of the regulations; am I
  reading that correctly?
  - A. Yes, that's correct.
- Q. And that portion -- those regulations deal with, what, are the prescriptions being issued correctly?
- A. Yes. That is part -- well, issued as far as everything required is being put on the physical prescription. Obviously, you know, I don't know what is happening inside a prescriber's office; however, what I do look at is, you know, is the required information on the prescription to be dispensed.
  - Q. Okay. And then there's -- after

Page 157 that there's various other portions of your 1 2. inspections, including DEA numbers, outdated drugs, prescription files. I'm going to go to 3 number 28, "Annual drug inventory. Has an 4 5 annual drug inventory been completed within the specified time periods?" Here you indicate 6 7 "Yes" and you provide some observation of when they were completed; is that right? 8 9 Α. Yes. 10 And am I reading this correctly that Ο. 11 in this inspection the Giant Eagle pharmacy 12 complied with the annual drug inventory 13 requirement? 14 A. Yes. 15 0. And then the second to last page of 16 this inspection deals with oral prescriptions 17 being reduced to writing, a positive identification system, qualified pharmacy techs 18 19 being employed. Are these just general areas of 20 your inspection that you checked to make sure 21 this pharmacy was complying with the 22 regulations? 23 Α. Yes. 24 38 references counseling. You 0. 25 checked here whether the pharmacy was complying

Page 158 1 with the counseling regulation; is that right? Go ahead. 3 Α. I'm sorry. Did you say 38 or --I'm sorry. 36. Sorry. 4 Ο. 5 Α. Okay. We talked about the counseling 6 Ο. 7 regulation before. Is this -- is this part of your inspection documenting compliance with the 8 9 counseling regulation? 10 Α. Yes. 11 And here there was no problem? Ο. 12 Α. Correct. 13 0. 38 deals with OARRS, including 14 access and whether they're requesting an OARRS 15 report when appropriate and whether they were 16 using delegates to request. And here you say 17 yes, the pharmacists have access, yes, that they 18 are requesting OARRS reports when appropriate, 19 and no, they're not using delegates. Is that 20 your enforcement of the regulations related to 21 drug utilization review that we went over? 2.2 Α. No. Well, that -- that portion is 23 specific to just OARRS, but, you know, as we 24 kind of talked about, OARRS is part of the drug

utilization review.

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- Q. All right. And then the remaining portion of your report deals with confidentiality, are there adequate safeguards to protect confidentiality. Here you had no problems with this pharmacy complying with the confidentiality rules?
  - A. That's correct.
- Q. And then you have Points of Emphasis and then Inspection Affirmations.

Do you see that?

A. Yes.

- Q. Now, in the summary you indicate that there's a warning of some sort and I was curious about the warning. Going through the report, I didn't see anything that would -- called a warning. What's this -- what does that mean there?
- A. So it's -- it's probably difficult to see just with the printed version, but if you go to page 6 of 10, there was a -- I believe this was a verbal warning, and, page 6 of 10 under Security, Section 5, and then number 3.
- Q. All right. And this relates to where the records of accountability were being

stored outside the pharmacy barricade but within the same physical location. Here's the reference to the warning. I missed that. So your observation was you inspected the cage in the basement of the grocery store which houses records. "The cage is secure however two U bolts on the right side of the door and a bolt mechanism on the left side of the door are accessible from the outside of the cage; could be removed and replaced without detection.

Corrective action. Ensure entire cage is both secure and tamper evident." Was that the purpose of the warning that's referred to at the end?

A. Yes.

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- Q. All right. So am I reading this right that this wasn't an actual break-in of the records area, you just saw a potential risk that somebody could break the bolts on the left side of the door and you wanted them to be more secure?
- A. Yes. So in reading this, it would have been not that they would break the bolts, but they could remove the bolts, remove records from within that cage, and then reattach the

Page 161 1 bolts. 2. 0. Okay. But that, actually, to your 3 knowledge, hadn't happened, you just said make it so that nobody could even remove the bolts? 4 5 Α. Correct. All right. And did this pharmacy 6 Ο. 7 comply with that request that they make those bolts more secure? 8 9 I can't answer that because I don't 10 believe I have looked at that cage since this 11 inspection. They were not given a written 12 warning. It was just a verbal warning. 13 0. Okay. All right. But otherwise 14 this inspection was good, am I correct, in terms 15 of all the areas we went over? 16 Α. Yes. 17 Did you consider it a good 18 inspection despite the -- they could have had 19 better bolts in the basement cage? 20 Yes, I did. Α. If you go two pages after that, I 21 2.2 think I've found your name on another document 23 dated September 18, 2019, BOP\_MDL2796412. 24 Α. Yes. 25 This says, "Property receipt," and I Q.

think you told me earlier this isn't necessarily an inspection, it's just going to the pharmacy, telling the pharmacist you want records here of Dr. Skiffey, it looks like, and they give you the records and you document it with a receipt, correct?

A. That's correct.

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- Q. All right. And at the end you say,
  "No issues found." Am I reading that right that
  you got the records you wanted, the pharmacy
  cooperated and gave you anything that you
  needed?
  - A. That's correct.
- Q. The last inspection report is actually a property receipt with your name -- it's the next page -- September 18th of 2019.

  It looks like the same date. It looks like you went to another Giant Eagle pharmacy in Warren and got records with respect to Dr. Skiffey again. So same type of thing going on here; it's not an inspection, it's picking up of records?
  - A. Yes, that's correct.
- Q. And, again, Giant Eagle pharmacists provided you with the records and cooperated

Page 163 1 with you? 2. Α. Yes. 3 Have you inspected Giant Eagle Q. pharmacies outside of Trumbull County? 4 5 Α. Yes. And am I correct that those 6 0. 7 inspections were generally good inspections with cooperative pharmacists, complying with whatever 8 9 you wanted and cooperating with you? 10 Α. Yeah. As far as I can recall, the 11 pharmacists are always compliant and helpful. 12 You know, there probably was a written warning 13 issued or a verbal warning to the best that I 14 can recall. 15 0. Agent DiFrangia, as far as you're 16 concerned, did Giant Eagle meet the requirements 17 for the licenses for its store and the renewal 18 of its licenses at all times with no license 19 ever being suspended or revoked? 20 Yeah. As far as I'm concerned, Α. 21 they have. 2.2 Ο. Did Giant Eagle pharmacies, from your perspective, meet the security requirements 23 24 of the regulations at all times? Yes. And if -- if there was a 2.5 Α.

minor portion where they didn't, corrective action was given and they would address that.

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- Q. In your experience, did you observe

  Giant Eagle pharmacies having even better

  controls than those required by the regulations?

  MR. WEINBERGER: Objection.
- A. Yeah, as -- as far as I can recall, you know, they were conducting their controlled substance inventories when required. I can't recall if they were doing it more.
- Q. All right. Do you recall, in your experience with Giant Eagle pharmacies, ever being sanctioned or suspended or cited for failure to meet the Ohio regulatory requirements?
  - A. As far as I'm aware, no.
- Q. Were Giant Eagle pharmacies adequately staffed based upon your involvement with them?
- A. Yes. From what I recall, they were.
  - Q. Did they have licensed pharmacists who -- who were experienced and qualified to work as pharmacists in the Giant Eagle pharmacies?

A. Yes.

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- Q. Did they have trained and supervised pharmacy technicians in the pharmacies based upon your inspections?
  - A. Yes.
- Q. Did the Giant Eagle pharmacies comply with the manner of processing prescription regulatory requirements, including performing drug utilization reviews, as far as you know?
  - A. As far as I'm aware, they have.
- Q. Based upon your experience, do you have any evidence that Giant Eagle pharmacies ever filled illegitimate prescriptions?
  - MR. WEINBERGER: Objection.
- O. You can answer.
  - A. Well, I guess -- yeah, they would have because I'm sure -- I believe I've seized prescriptions from a Giant Eagle that -- now specifically, Dr. Prommersberger prescriptions, that after reviewed by a medical expert and deemed issued for no legitimate medical reason, you know, we seized those because they were dispensed at a Giant Eagle pharmacy or, you, know, instances of that.

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Page 166 1 I see, but those types of 2 investigations, I think you told me earlier, 3 were also prompted by Giant Eagle and other pharmacists, correct? They --4 5 MR. WEINBERGER: Objection. 6 MR. BARNES: Can I finish my 7 question, Pete? 8 MR. WEINBERGER: I thought you were 9 finished. Sorry. 10 Going back to your prior testimony, 11 pharmacists, including at Giant Eagle, would 12 initiate leads and investigations for doctors 13 that they thought were behaving inappropriately? 14 Α. Yes. 15 0. And that from time to time would 16 lead to investigations and you would go back to 17 the pharmacies to get the prescription records, 18 correct? 19 That's correct. Α. 20 And then using pharmacy specialists Q. 21 and medical professionals in your 2.2 investigations, you were able to determine that 23 some of the prescriptions were illegitimate; is 24 that correct? 2.5 A. Correct.

Q. So is that what you mean, that in some instances you were able to later determine that some prescriptions were illegitimate because your investigation showed that that doctor was behaving inappropriately?

A. Yes.

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Q. Agent DiFrangia, based upon your experience with the Giant Eagle pharmacies and pharmacists, were the Giant Eagle pharmacies operating lawfully as far as you know?

MR. WEINBERGER: Objection.

- A. Yes. As far as I know, they were.
- Q. And were Giant Eagle and its pharmacists actively assisting law enforcement and the board with anti-diversion efforts?

  MR. WEINBERGER: Objection.
- A. Yes. As far as I've been involved with, they have.
- Q. I have similar questions for the other pharmacy Defendants, CVS, Walgreens, Walmart and Rite-Aid. Were those pharmacies and pharmacists at those pharmacies actively assisting law enforcement with anti-diversion efforts?

MR. WEINBERGER: Objection.

Page 168 1 Α. Yes. 2. 0. And similar to the question I just 3 asked you about Giant Eagle, were those other chain pharmacies operating lawfully as far as 4 5 you know? 6 MR. WEINBERGER: Objection. 7 Α. Yes. As far as I'm aware, they 8 were. 9 0. And were they, those other 10 pharmacies, the other pharmacy Defendants, they 11 were complying with the manner of processing 12 prescription regulations and the other 13 regulations that we just went over? 14 MR. WEINBERGER: Objection. 15 Q. I'm sorry? 16 As far as I'm concerned, yes, they Α. 17 were. 18 And were those other pharmacies also Q. 19 adequately staffed with trained and licensed 20 pharmacists and pharmacy techs? 21 MR. WEINBERGER: Objection. To my knowledge, they were. 2.2 Α. 23 And did these other pharmacies meet 0. 24 the security requirements in the Ohio regulations at all times as far as you're 2.5

Page 169 1 concerned? 2. MR. WEINBERGER: Objection. 3 Α. Yes. And did these other pharmacies also 4 Ο. 5 meet the requirements, the licensing requirements for its stores and for renewal of 6 7 its licensing for these stores at all times? 8 MR. WEINBERGER: Objection. 9 Α. Yes. As far as I'm aware, they 10 have. 11 Did you, in your experience, Agent Ο. 12 DiFrangia, including all your investigations --13 were you able to see a difference between chain pharmacies, on the one hand, and how they 14 15 operated, and independent pharmacies, on the 16 other hand, and how they operated? Did you see 17 any difference between the nature of controls at 18 one versus the other? Do you have any general 19 observations based upon your experience? 20 MR. WEINBERGER: Objection. 21 Yes. Based on my experience, I 2.2 would say that, you know, I think if you're 23 looking at a retail pharmacy, you may see a 24 situation where a pharmacist is the owner and 25 maybe they may not be inclined to turn away a

prescription due to potential monetary reasons or, you know, they don't want to lose the business, whereas, you know, I think that's a little bit -- it happens more with chain pharmacies because it's not the pharmacist's business, they're not the owner of the pharmacy, but they're, you know, protecting their license and their reputation. So I guess, based on that, you know, I think there is a little bit of a difference, the way they operate.

- Q. In your experience did you observe in your investigations diversion occurring at independent pharmacies?
  - A. Yes.
  - Q. More so than chain pharmacies?

    MR. WEINBERGER: Objection.
- A. Well, it depends what type of diversion. I happen to think -- this is just my own opinion. It's not based on data or anything of that nature. But sometimes I think that independent pharmacies are targeted by someone with fraudulent prescriptions. They may think that they're able to get something filled there. Some of them, they do fill it.

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Page 171 Some of them don't, you know, as far as stuff 1 of that nature. But I think the chain 2. 3 pharmacies, they definitely report to me more internal theft than any of the independent 4 5 pharmacies. 6 MR. WEINBERGER: Objection. Move to strike. 7 8 Ο. Have you ever investigated an 9 internet pharmacy? 10 No. No, not that I -- not that I Α. 1 1 recall. 12 MR. BARNES: I have nothing 13 further, Agent DiFrangia. I'd like to take a 14 five-minute restroom break. And I don't know 15 if my co-counsel for the other pharmacy 16 Defendants are going to have any questions. 17 Maybe they want to say so now or if they want to think about it over the break. 18 19 MR. BEISELL: I'll have a few 20 questions, Bob. MR. WEINBERGER: Well, I think I'm 21 2.2 entitled to cross this witness now before 23 anybody else asks further questions. 24 MR. BARNES: What do you base that 25 on, Pete? I thought we would finish the

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Page 172
    Defendants and then the Plaintiffs could go.
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                 MR. WEINBERGER: I disagree.
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                 MR. BARNES: Kate, do you have any
    questions?
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                 MS. SWIFT:
                             I'm happy to let Pete
    go first. That's fine. I don't know if I'm
6
7
    going to have questions or not.
                 MR. BARNES: All right. Is
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9
    everybody else happy to have Pete go first?
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                 MR. BEISELL: Fine by me.
11
                 THE VIDEOGRAPHER: We're going to
12
    go off the record at 1:39.
13
                      (Recess had.)
14
                 THE VIDEOGRAPHER: We are back on
15
    the video record at 1:49.
16
             EXAMINATION OF WILLIAM DIFRANGIA
17
    BY MR. WEINBERGER:
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                Agent DiFrangia, my name is Peter
           Q.
    Weinberger and I'm privileged to represent Lake
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    and Trumbull Counties in this case, and so I
21
    have a few questions to ask you on
22
    cross-examination, okay?
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           Α.
                 Okay.
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                 We have never met before, have we?
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           Α.
                 No.
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- Q. As I understand your work history, you have been an employee of the Board of -- Ohio Board of Pharmacy since November of 2016, correct?
  - A. Yes.

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- Q. So in terms of your observations relating to inspections and interactions with the pharmacy Defendants or their employees, as an agent for the Ohio Board of Pharmacy, that has occurred since November of 2016 to the present time, correct?
  - A. Yes.
- Q. And as I understand your -- let me ask you this: Since COVID, since the COVID pandemic, have the number of inspections, full inspections of pharmacies, been reduced in Trumbull County?
  - A. Yes, by me, definitely for myself.
  - Q. And why is that?
- A. Well, just with the pandemic, you know, we're trying to limit our exposure and, you know, limit everyone else's exposure to anything.
- Q. Okay. So in terms of your testimony that was elicited from you over the last ten

Page 174 minutes or so of questioning regarding your 1 2. views of the conduct of retail pharmacy Defendants in this case, they're limited to your 3 experience since November of 2016, correct? 4 5 Yes; however, I've had interactions 6 with pharmacists and pharmacies prior to that. 7 Right. But in terms of the kind of 0. inspection that you did, that you testified to 8 in 2018 at this Giant Eagle, that full 10 inspection, reviewing all these various systems, 11 pretty much your experience with respect to that 12 broad range of things that you looked at in your 13 inspections would be limited to your experience since November of 2016, right? 14 Α. 15 That's correct. 16 And when you do an inspection once a year, that's really a snapshot of a couple of 17 18 hours of experience with a pharmacy at that particular time, correct? 19 20 That's correct. Α. 21 And, sir, I can't see you. I don't 2.2 know if it --23 Oh, I'm sorry. My video went off. 24 Sorry. Is that better? 2.5 Α. There we go. Yes.

- Q. So when you do a full inspection, like you did in 2018, that's just really a couple-hour snapshot in time, correct?
  - A. Yes.

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- Q. And from what I can see from the records, at least -- from what I can see in the records, the only time that you did a full inspection of a pharmacy in Trumbull County was in 2018, correct?
- 10 A. Well, that's just for a Giant Eagle pharmacy.
- 12 Q. I meant a Giant Eagle pharmacy.
  13 Sorry.
  - A. Yes. Yes, that's correct.
  - Q. Now, do you have any information or recollection at this point as to how many full inspections you did since 2016 with respect to the other pharmacy Defendants in Trumbull County? Would it be a handful?
  - A. Yes. It's probably a handful for the other Defendants.
  - Q. And, likewise, with respect to those inspections, it would be a snapshot moment in time, assuming that the inspection took a couple of hours on one particular day in a year,

Page 176 1 correct? 2. Α. Yes, that's correct. 3 Now, it appears from your testimony, Q. and appropriately so, that you are very familiar 4 5 with the regulations of the -- that the Board of Pharmacy operates under with respect to 6 7 dangerous drugs or controlled substances, correct? 8 9 Α. Yes. 10 And controlled substances are 11 considered in the state of Ohio to be dangerous 12 drugs, right? 13 Α. Yes. 14 And they are dangerous drugs because Ο. 15 they can be addictive, correct? 16 I think they're dangerous drugs --17 controlled substances are dangerous drugs because they're issued by a prescriber and 18 19 they're dispensed from a pharmacy, different 20 from something that you could purchase over the 21 counter. But particularly with respect to 2.2 Ο. 23 opioid prescriptions or opioid prescription 24 drugs, they are dangerous because they can be 2.5 addictive, correct?

Page 177 1 Yes. Α. 2. Ο. And because these drugs are 3 dangerous and can be addictive, they have a propensity or carry a risk of being diverted, 4 5 correct? 6 Α. Yes. 7 And if you have addiction and 0. diversion, that leads -- that can lead to 8 9 problems with the safety associated with those 10 drugs, right? 1 1 Α. Sure. 12 In fact, the regulations that you 1.3 enforce for the Board of Pharmacy with respect 14 to opioid prescriptions are intended, if 15 complied with, to save lives, correct? 16 I would assume that's what the 17 intention is. 18 These regulations are intended to Ο. save lives and attempt to reduce the risk of 19 20 misuse or abuse of opioid prescription drugs, 21 correct? 2.2 Α. That's how I interpret many of them. 23 24 Ο. And so any -- would you agree that 25 any retail pharmacy chain who has a license to

Page 178 dispense opioid prescription drugs should 1 2. realize that compliance with the laws is important in order to save lives and reduce the 3 risk of opioid misuse or abuse, correct? 4 5 MR. BEISELL: Objection. 6 Α. Yes. 7 Now, are you familiar with the 0. Controlled Substances Act, the federal 8 9 Controlled Substances Act and its regulations? 10 Α. Yes. 11 And is it your job to enforce the Ο. 12 Controlled Substances Act and its regulations as 13 an agent of the Board of Pharmacy? 14 I think it -- parts of it fall 15 within our duties. I mean, we are tasked with 16 enforcing United States Federal Code, so I 17 would think that kind of falls within it. 18 But would you agree with me that Q. 19 primarily your role as an agent for the Board of 20 Pharmacy is to carry out the obligations or, I 21 should say, enforce the laws of the State of 2.2 Ohio and its regulations? 23 Yeah, I would say that's our Α. 24 primary goal, is to enforce the rules of the 2.5 State of Ohio.

Q. Earlier Mr. Barnes asked you about Defendants' DiFrangia Exhibit 9.

MR. WEINBERGER: James, can you bring that exhibit up on the screen?

- Q. And if you want to pull that out of your notebook or you can look at the screen together with me. However you want to do it, Agent DiFrangia, is okay with me.
  - A. I'll just use the screen.
- Q. All right. This DiFrangia

  Defendants' Exhibit 9 apparently is a document that the pharmacy Defendants received from the Board of Pharmacy pursuant to a subpoena that they issued on the board.

Do you got that so far?

A. Yes.

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- Q. All right. And when you were asked about this document by Mr. Barnes, you told him that this appears to be how one might approach investigating a prescribing issue with a prescriber. That wasn't your exact testimony but did I basically get your testimony correct?
  - A. Yes.
- Q. All right. I want to go through this with you -- well, let me ask you this:

Looking through this document -- and, James, if
you would go back to the full document,

please -- it has two sections. One is Data

4 Anomalies and the other is a General Workflow.

First of all, can you see that on your scene?

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- Q. And looking at the 21 items of data anomalies, do these appear to be red flags regarding opioids prescribed by doctors that are within the definition of red flags, as you understand it?
  - MR. BARNES: Object to form.
- A. I would say that they are -they're anomalies. I don't know that they're
  necessarily red flags, but when you start to
  put some of them together, then you could be
  looking at a potential red flag prescribing
  incident.
- Q. Right. And so when you're -- when you're looking at a red flag prescribing incident, what you're looking for are signals that a particular prescription might not be being prescribed for a legitimate medical purpose, correct?
  - A. That's correct.

- Q. And this list appears to be an analysis or things that one might analyze in looking at a prescriber's prescribing habits, correct?
  - A. Correct.

- Q. So if a prescriber has a large total number of patients for which they're prescribing opioids, that's a potential anomaly or red flag, correct?
  - A. Yes.
- Q. And if -- the analysis of the daily patient breakdown, do you know what that refers to?
- A. Yeah. My guess is that's probably relating to, you know, if you could break it down to how many patients are being seen in a day for controlled substances.
- Q. Right. And the large overall volume of prescriptions, what does that refer to?
- A. That's just a -- that's just your lump sum of controlled substance prescriptions issued by a prescriber over a period of time.
- Q. And number 4 seems pretty obvious,
  "Patients with drug related criminal histories."

  It is what it says, right?

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Exactly. Α.

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- 0. Now, I'm interested in number 5, "Prescribing of similar drugs in groups," and there's a subsection, "Cocktails." What does that refer to?
- My guess, the way I'm interpreting this, is let's say a prescriber is prescribing a short-acting, pain-relieving medication in addition to a long active -- long-acting, pain-relieving medication.
- Now, why is that a potential anomaly 0. or red flag?
- Α. Well, you know, it could be warranted if needed, but I quess if it's something that happens over time, over multiple patients, then it could be concerning that instead of maybe a segment of patients getting one large amount of prescription medication, they're getting a prescription for two medications, you know, potential opiates or something of that nature.
- Ο. Number 6 -- and the cocktails, there's actually a Section 9 that deals with drug cocktails. We'll get to that in a second.
- 2.5 Number 6 is "Prescriber at unusual distance from

pharmacy." Why is that or what is it about that that makes it an anomaly or potential red flag?

- A. Really just based on maybe the patient lives near the pharmacy but they go -they travel an hour to see a prescriber when in theory they probably pass several prescribers' offices in doing so. So what is -- what is -why is that patient driving an hour, passing several different prescribers' offices, to see that one prescriber, and then maybe coming back to a pharmacy near their residence to get the medication dispensed?
- Q. Meaning that there's a -- that might raise the suspicion that the subscriber is either a pill mill doctor or someone who is overprescribing to certain patients, true?
  - A. Yes, true.

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- Q. Number 7, "Purchasing drugs with cash (when some form of insurance, Medicare or Medicaid, was previously used)." Why is that an anomaly or red flag?
- A. Well, if you have commercial insurance or, you know, some sort of public insurance, you would use that instead of paying money out of your pocket. So, you know, why --

it leaves one to ask why are they paying cash when they have insurance for prescription medications.

Q. Is it fairly well-known in the law enforcement sector of our country that payment of prescription drugs in cash is often related to potential illegal use of opioids?

MR. BEISELL: Objection.

- A. Yeah. My opinion is that it is.
- Q. When drugs are -- when opioid prescription drugs are diverted and the diversion is that the patient who's picked up or had the prescription filled is then taking all or part of that prescription and selling it on the streets, is it well-known among law enforcement that those transactions take place utilizing cash?
  - A. Yes.

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- Q. And the people that are filling those prescriptions and obtaining cash payments when they divert those prescription pills on the streets are often also people that have an abundance of cash that can then be used to pay for the prescriptions, correct?
  - A. Yes. That's possible.

- Q. Now, number 8, "Multiple prescriptions for similar substances (oxycodone or oxycodone APAP)," what does that stand for?
- A. Oxycodone APAP is an abbreviation for oxycodone acetaminophen.
- Q. So that's a combination oxycodone drug, right?
  - A. Yes.

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- Q. Now, why is it that multiple prescriptions for similar substances is an anomaly or potential red flag?
- A. I think to me I interpret number 8 as being similar to number 5, where, you know, you may have a prescriber that is prescribing one patient oxycodone and then also giving a prescription for oxycodone acetaminophen.
- Q. Now, number 9 is "Prescribing drug cocktails (aka Trinity or Holy Trinity), combinations of benzodiazepines with opiate based drugs." And then there's a list of other drugs, hydrocodone, oxycodone, a pain reliever, then drugs like benzodiazepine, which are anti -- those are anti-anxiety drugs, right?
  - O. And a muscle relaxant. That's the

Yes.

Page 186 1 generic name for Soma, correct? 2. Α. Yes. 3 0. And why is this a potential red flaq? 4 5 Well, you know, again, based on my Α. 6 opinion, my conversations with pharmacists and 7 prescribers, these are just -- these are -it's a combination that's kind of, I guess you 8 9 could say, frowned upon in the medical community. I'm not a doctor. However, that's 10 11 just the information that's been told to me by, 12 again, prescribers and pharmacists. You know, 13 there's some potential negative interactions 14 that could happen with this combination, but 15 that's just information that's been relayed to 16 me as an agent. 17 Right. And that's because it's Q. 18 well-known in the medical community, in the law 19 enforcement community, that the combination of 20 these three drugs are an indication of abuse and 21 potential diversion, correct? 2.2 MS. SWIFT: Objection. Foundation. 23 MR. BARNES: Object to the form of 24 the question. 25 O. Go ahead. You can answer.

- A. Yes, that's correct.
- Q. Number 10, "Prescriber does not fit the scope of practice for drugs prescribed," what does that mean?
- A. You know, that's a prescriber that's maybe prescribing a large amount of medication that's just not in their scope. So I guess as an example, like a dentist that's prescribing a large amount of amphetamine salts. You know, they're scheduled medications, they're stimulants. They really don't fit their -- fit into their scope of practice.
  - Q. Can you give me any other examples of that?
  - A. Yeah. You know, maybe a -- you know, it could be -- it could be that a family doctor or family physician prescribing a very large amount of opiates. They're permitted to prescribe those; however, you know, it could be so many that, you know, potentially out of their scope of practice.
- Q. So these other -- I'm going to group these together and just ask you, from 11 to 21, are these all well recognized by law enforcement

Page 188 1 and pharmacists as red flags that might indicate 2. a suspicious subscription? 3 MR. BARNES: Object to form. Yes, I believe they are. 4 Α. 5 And from your experience in law 0. 6 enforcement, going back many years before you 7 were with the Board of Pharmacy, was it your experience and knowledge that these 21 described 8 9 anomalies were fairly well known in law 10 enforcement as potential red flags for 11 suspicious prescription or a problematic 12 prescription? 13 MR. BARNES: Object to form. 14 Α. Yes. 15 Now, from your knowledge and Q. 16 experience, how many years has it been known 17 that these are -- these are all potential red 18 flags or anomalies associated with opioid 19 prescriptions? 20 MR. BEISELL: Objection. 21 Well, you know, I can really only -- I can really only account for my own -- my 22 23 own knowledge and my own experience, and 24 that's -- that's probably going back to about 2.5 2013, 2014.

Page 189 All right. Fair enough. 1 0. 2. Now, looking at these -- at these 21 items of potential red flags, would it be 3 fair to say, Agent DiFrangia, that the retail 4 5 pharmacy chains have information regarding all of these potential anomalies within their own 6 7 dispensing data? MR. BARNES: Object to form. 8 Lack 9 of foundation. MR. WEINBERGER: I'll withdraw that 10 11 question. 12 You have indicated that during the 13 course of your full inspections of pharmacies, 14 you have a chance to look at the pharmacy's own 15 dispensing data, correct? 16 Α. Yes. 17 And I'm assuming that what that 18 means is that you can look into their computer 19 systems, look at their screens and look into 20 their computer systems and see what dispensing 21 data is available, correct? 2.2 Α. Yes. Including some of the fields of data 23 0. 24 that's available through the computer, right? 2.5 Some of the fields. Α.

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Page 190 So do you know, Agent DiFrangia, that for -- well, let's just say for the last 20 years whether or not the retail pharmacy Defendants in this case have been storing dispensing data in their systems? MR. BARNES: Object to form. I'm sorry. Do I know that? Α. Ο. Right. Α. No, I don't know that. Since 2013 have you known that the 0. retail pharmacy chains store their dispensing data in their systems? MR. BARNES: Same objection. Ο. Go ahead. You can answer. Α. Yes, I'm aware they store their

- 16 dispensing data in their -- in their dispensing 17 systems.
- 18 In the course of your interaction Ο. 19 with any of the retail pharmacies during your 20 annual inspections, have you ever inquired of 21 any of the pharmacists whether they are provided with corporate analysis of dispensing data? 2.2
  - Α. No, I don't know that I've ever asked that during an inspection.
    - Have you ever asked them whether Ο.

Page 191 1 they receive reports from their corporate 2. offices on how to use -- or policies on how to use dispensing data to analyze the data 3 anomalies and red flags that are listed on 4 5 Exhibit 9? I have never asked that of them. 6 Α. 7 If there was dispensing data that 0. could be analyzed to look at these various 8 9 anomalies, that would be helpful to the 10 pharmacist in carrying out their duties to only 11 dispense prescription opioids that are for 12 legitimate medical practice, correct? 13 MR. BARNES: Objection. Lack of 14 foundation. You know, I don't know if that 15 Α. 16 would be helpful because I'm not a pharmacist. 17 Q. All right. Fair enough. 18 But at least -- if the dispensing 19 data provided a window into the ability to 20 analyze any one of these 21 red flags or 21 anomalies and that could be provided to the 22 pharmacist, that would potentially be helpful 23 to the pharmacist in carrying out their job, 24 correct? 2.5 Same objection. MR. BARNES: Asked

Page 192 1 and answered already. 2. It could be, but again, I'm not a pharmacist and I don't know that I could answer 3 that. 4 5 Well, you're familiar with the Ο. obligation -- what's called the corresponding 6 7 obligation or responsibility on the part of the pharmacist, correct? 8 9 Α. Yes. 10 I mean, the pharmacist, in the chain 11 of dispensing the drugs, is the last line of 12 defense, correct? 13 MR. BARNES: Object to form. 14 Α. Yes. The answer is yes? 15 Q. 16 Yes. Α. 17 The pharmacist receives a Q. 18 prescription that's presumably written or 19 ordered by a physician and then has to undertake 20 his or her own corresponding responsibilities to 21 ensure that that prescription is filled in 22 accordance with the law, correct? 23 Α. Yes. 24 And that is particularly true with Ο. 25 respect to dangerous drugs, such as opioid

Page 193 prescriptions, correct? 1 2. Α. Yes. Because as the last line of 3 defense -- the pharmacies and the pharmacists is 4 5 the last step in providing prescription opioids 6 to the public, correct? 7 MR. BEISELL: Objection. Form. Α. 8 Yes. 9 Now, with respect to these data 10 anomaly and red flags on DiFrangia Defendants' 11 Exhibit 9, does OARRS -- does the data in OARRS 12 have the potential for providing the information 13 to analyze these data anomalies? 14 Yes, it does. Α. 15 0. And earlier you testified that there 16 are limits in OARRS in terms of what a 17 pharmacist can obtain versus what you can obtain 18 by way of either a subpoena or by utilizing 19 OARRS as an agent for the Board of Pharmacy, 20 correct? 21 Α. Correct. 2.2 And have you, Agent DiFrangia, ever 23 analyzed a retail pharmacy chain's data, dispensing data, to see how much information 24 that data has that might identify some of these 25

data anomalies?

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- A. I mean, I have reviewed data for retail pharmacies, but I don't know that I've necessarily reviewed it for data anomalies.

  You know, I've reviewed it for trying to find a certain prescription or something of that nature, but as far as I recall, I don't know that I've ever reviewed a retail chain pharmacy. I've done retail independent pharmacies but not a retail chain pharmacy.
- Q. So when you testified earlier that with respect to your 2018 full inspection of the Giant Eagle pharmacy, that you looked at and approved their dispensing data system, that was done on a very limited basis, correct?

MR. BARNES: Object to form.

- A. Yes. It is a -- it's a limited basis.
- Q. Well, when you say "limited," what does it mean? I mean, let's assume that that inspection, and I think the records reflect, was about three and a half hours to answer all of those 40 or so questions that are in that form. How much time did you actually spend actually looking and reviewing dispensing data of the

Page 195 1 pharmacy, of that particular Giant Eagle 2. pharmacy? 3 Α. I can't recall. A matter of a minute or two? 4 0. 5 I can't recall. You know, we 6 looked at the dispensing software. I think in 7 that inspection I reviewed a patient's profile, but, you know --8 9 Well, with respect to the latter 10 part of that answer, that's -- I'm glad we got 11 to that. You said -- you made the comment that 12 you believed that the Giant Eagle, based upon 13 that inspection, complied with the requirements 14 of the patient profile in terms of the data 15 that's retrievable for that, correct? 16 Α. Yes. 17 That's what you testified to, right? Q. 18 Α. Yes. 19 But what you actually did is you Ο. 20 looked at one patient, one patient's profile, 21 correct? 2.2 Α. Yes. You didn't look at or review 20 23 Ο. 24 patients, 50 patients, a hundred patients, and look to see whether or not the drug utilization 25

Page 196 profile was accurate or proper, correct? 1 2. MS. SWIFT: Object to the form. 3 Leading. MR. WEINBERGER: Of course I'm 4 5 leading. I'm cross-examining him. MS. SWIFT: Okay. Well, if your 6 7 position is that this is a hostile witness to Plaintiffs -- is that what you're saying, Pete, 8 9 the Board of Pharmacy is a hostile witness? 10 MR. WEINBERGER: No, I'm not saying 11 he's a hostile witness, Kate. What I'm saying 12 is that you've called him on -- you've called 13 him for deposition as if under direct and I'm entitled to cross-examine the witness. 14 15 MS. SWIFT: My objection stands. 16 Leading. MR. WEINBERGER: Okay. Very good. 17 18 Q. So you looked at one drug utilization patient profile, correct? 19 20 MS. SWIFT: Objection. 21 Α. From what I recall, yes. 2.2 And then you made a judgment based Ο. upon that one review -- and I'm not criticizing 23 24 you for that, but I just want to be clear. You made a judgment based upon the review of one 25

Page 197 patient profile drug utilization review that 1 2. that particular Giant Eagle store was in compliance, right? 3 4 MR. BEISELL: Objection. 5 MR. BARNES: Object to form. 6 Α. Typically I follow up with 7 questions, such as can you provide this information, how long, how far back does it go, 8 9 are you able to provide it, and, you know, I 10 take all that into account. 11 Fair enough. Ο. 12 But in terms of actually looking at 1.3 what a particular pharmacist working for Giant 14 Eagle pharmacy actually did or does, you were 15 looking at, first of all, one snapshot in time, 16 and in terms of the patient profile, one 17 patient profile, correct? 18 MR. BARNES: Objection. Asked and 19 answered. 20 Object to form. MS. SWIFT: 21 0. You can answer. 2.2 Α. Yes, it's a snapshot in time. 23 Now, do you believe that a retail 0. 24 chain pharmacy's dispensing data could develop a prescriber profile based upon that data? 2.5

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Page 198
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                 MR. BARNES: Objection.
                                           Lack of
2.
    foundation.
                 I believe that it could.
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          Α.
                 MR. APPEL: Pete, this is Henry
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    Appel. Do you mind if we take a few minutes
    just so I can touch base with my client
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7
    briefly, take five minutes, ten minutes?
                 MR. WEINBERGER: Sure.
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                 MR. APPEL: Thank you.
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                 THE VIDEOGRAPHER: We're going off
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    the record at 2:27.
12
                      (Recess had.)
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                 THE VIDEOGRAPHER: We are back on
    the record at 2:37.
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15
    BY MR. WEINBERGER:
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                 Agent DiFrangia, I would like you to
           Ο.
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    take a look at Edwards Exhibit 10.
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                 MR. WEINBERGER: And, James, these
    aren't Bates stamped, but what we're going to
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    do is we're going to look at 4729-5-20. So
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    it's a couple pages in. There we go.
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                 Agent DiFrangia, do you have
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    4729-5-20 in front of you from Exhibit 10?
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          Α.
                I -- yes.
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           Q.
                 Thank you.
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So you were asked a whole lot of questions by Mr. Barnes about this particular section of the Ohio regulations entitled "Prospective Drug Utilization Review."

With respect to Sections A -Section A, do you know whether or not this
particular section has been in effect for about
20 years?

A. I don't know.

- Q. I'm particularly interested in Section A(4), which is drug-drug interactions, and let me ask you, does that include what you testified to regarding in Exhibit -- DiFrangia Exhibit 9, when we looked at drug cocktails?
  - A. No. I don't know.
- Q. Well, isn't it true that the trilogy drugs that are described in Exhibit 9, which is a combination of an opioid, an anti-anxiety drug and a muscle relaxant, are red flags because of the way in which they interact together?
- A. Yeah. From what I've been told by, you know, prescribers and pharmacists.
- Q. So knowing that, would it be fair to say that drug-drug interactions under Section A(4) refers to that -- to cocktail drugs, as an

Page 200 1 example? I don't know if that refers to 2. Α. cocktail drugs. 3 If it does, that should be part of a 4 5 pharmacy's drug utilization review when filling an opioid, correct? 6 7 I don't know if it has any reference to that trilogy cocktail that we 8 9 discussed. 10 I want to go to the second page of 0. this and that's Section G of 4729-5-20. This is 11 12 the section that you testified earlier in my 13 cross-examination of you that relates to the 14 corresponding responsibility of the pharmacist, 15 correct? 16 Α. Yes. 17 And it specifically says in the 18 second sentence, "The responsibility for the 19 proper prescribing is upon the prescriber, but a 20 corresponding responsibility rests with the 21 pharmacist who dispenses the prescription, " 2.2 correct? 23 Α. It does say that. 24 "Based upon information obtained Ο. 2.5 during a prospective drug utilization review, a

Page 201 pharmacist shall use professional judgment when 1 2. making a determination about the legitimacy of a 3 prescription, " correct? I've read that correctly? 4 5 Α. Yes. 6 0. And it goes on to say that if 7 there's any -- if there's any concern about whether or not a prescription is questionable, 8 9 doubtful, or suspicious, the pharmacist is not 10 required to fill the prescription, correct? 11 It does say that, yes. Α. 12 That's what we're talking about when 0. 13 I earlier asked you about the pharmacy and the 14 pharmacist being the last line of defense with 15 respect to opioid prescriptions, correct? 16 I mean, in my opinion I think 17 that's accurate. 18 All right. Now, can we agree that Q. 19 when the pharmacist is exercising his judgment 20 in fulfilling this corresponding responsibility, the pharmacy that he works for has the 21 22 obligation of giving the pharmacist adequate tools to be able to do his job, correct? 23 24 MR. BEISELL: Objection. 2.5 MS. SWIFT: Objection. Calls for a

Page 202 1 legal conclusion. 2. Ο. You can answer. 3 Α. I don't know. Well, with respect to information 4 Ο. 5 coming from dispensing data that the pharmacist might want to utilize to exercise his 6 7 corresponding responsibility, the information is only as good as that which is provided to the 8 9 pharmacist by his employer, the pharmacy, 10 correct? 11 MS. SWIFT: Object to the form. 12 I don't -- I don't know what a Α. 1.3 pharmacist would want or need because I am not 14 a pharmacist. 15 Well, you do know that OARRS --16 access to the OARRS data for as long as it's 17 been accessible, which doesn't go back 20 years but I think goes back something less than that, 18 19 is -- has the potential for providing important 20 information to the pharmacist in fulfilling his 21 corresponding responsibility, right? 2.2 Α. Yes. 23 And if the pharmacy that employs him 24 has information that's similar to what is 2.5 contained in OARRS and has had that information

- for years long before OARRS was in existence, that information could potentially be helpful to the pharmacist in carrying out his corresponding responsibility, true?
- A. You know, again, I don't -- I don't know if that would be helpful because, you know, I think that would be a question geared for a pharmacist.
- Q. Well, certainly your inspection and that of the other agents doesn't look at that question, does it?
  - A. Which question?

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- Q. The question of whether or not the retail pharmacy chain that employs these pharmacists is giving the pharmacist adequate information from their dispensing data to help that pharmacist carry out his corresponding responsibility.
- A. I mean, that specific question is not asked during an inspection.
  - O. Okay. And --
- MR. BARNES: Excuse me. I was muted. I did have objections to the form of the last two questions.

MR. WEINBERGER: That's fine. I'm sure they'll note it in the record and I'll recognize it.

- Q. You mentioned with respect to the December 18, 2018 report from your inspection of the Trumbull County Giant Eagle that this format, this computerized or computer-generated format, is a new format that is very helpful in helping you document inspections, correct?
  - A. Yes.

- Q. And from looking at prior inspection reports that were not using this system, you have generally an idea of what those reports look like, right?
  - A. Yes.
- Q. And those were handwritten reports that had a column of items that I guess the inspector might be considering in doing the inspection, correct?
  - A. Yes.
- Q. Looking at drug utilization review reports or dispensing data is not a part of any of the 40 sections or description of 40 items that they might inspect in those old reports; are you aware of that?

Page 205 MR. BARNES: Object to form. 1 2 Α. No, I'm not aware of that because 3 I've never used those old handwritten reports. So of your own personal knowledge, 4 0. 5 Agent DiFrangia, would it be fair to say that 6 you have no idea prior to 2016 whether any of 7 the inspectors were looking at dispensing data or drug utilization reports as they might be 8 9 accessed by a pharmacist during their 10 inspection? 11 Α. I mean, I'd have to guess that they 12 were. 13 0. We don't want you to guess. But I don't know for sure because 14 15 I've never conducted an inspection prior to 16 2016. 17 All right. Now, I want to talk with 18 you a little bit about this December 18, 2018 19 inspection report, so that's in Exhibit 30 --20 Exhibit 17 towards the back. Can you pull that 21 out and put it in front of you? 2.2 Α. Sure. 23 Let me know when you're there. We 0. also have it up on the screen. Do you got it? 24 25 I'm still going through the pages Α.

Page 206 1 here. 2. Yes, I have it up. I'm sorry. 3 December --18th, 2018. 4 0. 5 Α. Okay. 6 0. I want to go through the process of 7 this kind of inspection. And we can agree that this is the only full inspection that you did of 8 9 a Giant Eagle store in Trumbull County since you 10 were a Board of Pharmacy agent, correct? 11 Yes. As far as I can recall it is. Α. 12 So do you -- is there -- do you have 0. 13 a laptop with you when you're doing this? 14 Α. Yes. 15 0. All right. And then it has a number 16 of questions or drop-down items that you can 17 utilize on the computer software? 18 Α. Yes. 19 And according to the second page of 20 the report, this -- well, let me ask you this: When it says "start" and "end, December 18, 21 22 2018, 12:45 p.m. - 3:36 p.m., what does that 23 mean? 24 That is pretty much the time that Α. you initiate the inspection, the software on 25

Page 207 the computer, and then the end time is, at the 1 2. end when you hit "finalize," it sends an e-mail 3 to myself and then it also sends an e-mail to -- to the staff pharmacist which is there. 4 It signifies the minute you hit that finalize 5 6 button. 7 So do you have any idea what time you got to the -- to this particular pharmacy, 8 9 what time you arrived? 10 No, I don't. Α. 11 Do you have any idea what time you Ο. 12 left? 13 Α. No. 14 Do you have any idea how long the Ο. 15 inspection took place? 16 Well, the inspection took place 17 from about that time. 18 So this was an inspection for how Q. 19 long? 20 From about 12:45 to 3:36. Α. 21 0. So about four hours approximately? I mean, give or take, but no. It's 22 Α. -- I mean, we're looking at not quite three 23 24 hours that you could say the inspection was actually occurring, but, I mean, was there time 25

Page 208 that I spoke with the pharmacist before or 1 spoke with him after, I really don't recall, 2. 3 but that's generally what happens during inspections. 4 5 In these retail pharmacy chain stores like Giant Eagle, is there -- do you know 6 7 whether or not they have a video system where they are taking videos of what's happening 8 9 within the pharmacy? 10 Yeah. This pharmacy, I believe 11 they do have a video system. 12 Have you ever looked at any of the 0. 13 video system tapes? 14 For this pharmacy? Α. 15 Q. Yes. 16 Not that I recall. Α. 17 The time frame between 12:45 and Q. 18 3:36 p.m., from your knowledge, in terms of 19 inspecting these retail pharmacy chain stores, 20 is that a particularly busy time or a slow time? 21 I think that's probably more of a 2.2 busier time. Why is that? 23 0. 24 Α. Well, you've got people that maybe on their lunch break they're trying to get 25

their prescriptions filled, and then towards the end of their shift they're coming in to get their prescriptions filled.

- Q. Setting aside the Giant Eagle pharmacy, which is a part of a large grocery store, with respect to CVS and Walgreens and Rite-Aid, you've been in all their stores?
  - A. Yes.

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- Q. Do they have, generally speaking, a busier time than that from your experience?
- A. No. I think it's -- I think they're pretty steady for the most part. I mean, the evenings are less busy. The mornings I think are busier. They're getting, you know, prescriptions that came in overnight or things from late in the day the prior day. But, I mean, generally it -- it really depends. They're pretty steady throughout the day.
- Q. Well, have you ever looked and studied any of the videos of -- by the way, does CVS and Walgreens also have video systems that -- particularly with respect to their pharmacies?
- A. Yeah. I'm sure they have in some pharmacies. I don't know if they have them in

Page 210 1 all. Have you ever looked at any of the 2. Ο. CVS or Walgreens or Rite-Aid videos? 3 During inspections? 4 Α. 5 Ο. Yes. No, not during inspections 6 Α. 7 generally. Okay. So when you, for example, 8 0. 9 made the conclusion that there was adequate 10 staffing, that was based upon your observations 11 during this time frame at the Giant Eagle store, 12 right? 13 Α. Yes. 14 You never looked at the video for 15 the whole day of this store to determine whether 16 or not there was adequate staffing, right? 17 No, I did not. Α. 18 Nor have you ever done that with respect to any of the other retail chain 19 20 pharmacies that you inspected, correct? 21 That's correct, I haven't. 2.2 Ο. Now, in the course of investigating 23 a potential -- let me ask you this: You were 24 involved in an investigation that resulted in testimony in the case of Carrie Allen, who was a 25

Page 211 Rite-Aid technician who was stealing from the 1 2. pharmacy. 3 Do you recall that case? 4 Α. Yes. 5 And you -- to perform that 6 investigation and to work up the case, you had 7 installed an Ohio Board of Pharmacy surveillance camera, correct? 8 9 Α. Yes. And you were able to use that camera 10 11 in order to catch the pharmacist, Carrie Allen, 12 or the technician, stealing hydrocodone pills, 13 right? 14 I think it was -- I think it was 15 alprazolam pills, if I'm thinking of the 16 correct person. 17 Q. From the information I have, it was 18 both alprazolam and hydrocodone. Does that 19 refresh your memory? 20 I mean, we're talking about a 21 Rite-Aid pharmacy in Newton Falls? 2.2 Ο. Yes. 23 Α. Okay. 24 Did that Rite-Aid pharmacy have 0. 25 video cameras of its own?

Page 212 1 I think they did, yes. Α. 2. Ο. Why did you have to install your own 3 cameras? Well, their cameras were not --4 Α. 5 from what I recall, they were limited and they only covered a limited portion of the pharmacy, 6 7 and, you know, we realized that there was an issue with the hydrocodone and then the 8 9 alprazolam, so my camera was focused 10 specifically on those areas. 11 So let's go back -- let's go back to 12 this part of Exhibit 17, your December 18, 2018 13 inspection report. Going to page 3 of 10, 14 before when I asked you how many detailed 15 patient profiles you looked at in order for you 16 to determine whether this particular store 17 complied with the regulations regarding detailed 18 patient profile, you said you looked at one 19 patient's profile, correct? 20 Α. Yes. 21 And the patient profile that you 22 looked at was a patient who you were investigating, right? 23 24 I don't know that I was Α. investigating the patient, but he was -- the 2.5

Page 213 investigation was surrounding him. I don't 1 2. think it was against him. 3 A complaint about a HIPAA violation? 4 Α. Yes. 5 And so you asked the pharmacist --0. 6 did you ask the pharmacist to pull up the 7 patient profile or did you do it yourself? I would have asked them. 8 9 And the second question under Record 0. 10 Availability says, "Can the pharmacy produce 11 three years of dispensing records within three 12 days?" And the answer was "Yes." How did you 13 get that information? From what I recall, I probably just 14 Α. 15 asked it. 16 Okay. So you didn't -- you didn't Ο. 17 ask anybody to go into the records or into the 18 data on the computer system to confirm that they could do that, correct? 19 20 No. I just asked them if they were Α. 21 able to produce records within three days. 22 Ο. Now, was that -- were those -- for example, were those very questions questions 23

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that would have been asked by an inspector prior

to 2017, when this new system of inspection and

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Page 214 computerized system went into effect? 1 2. Α. I don't know for sure. 3 Let's go to the next page. You testified about the shared dispensing software, 4 5 2.3.4, and you -- I think you testified and -that the shared dispensing software -- "Is there 6 7 a real time online system used for review and transfer of dispensing data?" The answer is 8 9 "Yes." And then there's an observation that 10 says "Yes." What does that mean? 11 Well, again, that -- that relates Α. 12 to, you know, is it real time for the other 13 vacancy, real time what this patient has been dispensed and, you know, if they can see for 14 15 pharmacies within their -- within their chain. 16 And did you actually see the data 0. 17 yourself? 18 Α. No. Again, this is something that 19 I would ask the pharmacist. 20 So you didn't -- you didn't confirm Ο. 21 it yourself by looking at the computer screen, 22 you were just relying on the pharmacist's 23 answer? 24 Α. Correct. And going to page 7, number 10, 25 Q.

Page 215 Improper Dispensing. "Is there evidence to 1 2. indicate that a prescription has been dispensed 3 improperly? And your answer was "No." What was that based -- what was that answer based on? 4 5 That's generally based on what I typically will do is review some of the hard 6 7 copy prescriptions. How many did you review that day? 8 9 Α. I don't know. 10 You didn't look at any of the 11 dispensing data to determine whether or not any 12 prescription was dispensed improperly? 13 MR. BARNES: Objection. Asked and 14 answered. 15 Ο. What's your answer? 16 I don't know. I don't recall. You 17 know, I -- I was thinking about the 18 investigation that I was reviewing and, you 19 know, I just don't know. I don't know what I 20 looked at exactly. 21 The next question, which asks about 2.2 insufficient supervision is based upon -- was it 23 based upon your observations during that couple 24 hours that you were there or something else?

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That's based on my own

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Α.

Page 216 observations. Well, did you -- did you ask for the Ο. data on the number of opioid prescriptions that were filled during any particular time frame at that store? Α. No. And did you ask for information as 0. to how many pharmacists or pharmacy techs were working at the store at any particular point in time during the day? Well, yeah, that I would have documented on the first page, everyone that was there.

- Q. So did you ever compare the number of prescriptions filled to the number of pharmacists employed at the store?
  - A. No.

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Q. So the way to really determine whether or not there was adequate supervision and sufficient employees to fill -- to properly and safely fill prescriptions would be to look at the number of prescriptions filled and compare that with the number of pharmacists or pharmacy techs employed at the store, right?

MR. BARNES: Objection. Lack of

foundation.

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- A. I don't know if that's -- that's the way that has to be reviewed.
- Q. Well, does the Board of Pharmacy ever look at those sorts of metrics, meaning number of prescriptions filled versus number of pharmacists or pharmacy techs employed, in order to determine whether there's adequate personnel or supervision?
- A. For different types -- for different investigations, such as an error in dispensing, we record the amount of prescriptions dispensed for a particular day in which a suspected error may have occurred.
- Q. You know, you were asked a question to compare the conduct of independently owned pharmacies versus these retail chain pharmacies, and your answer was something along the lines of that the independent chain pharmacy that's family owned or individually owned might be more incentivized to fill more prescriptions. Did I summarize your testimony correctly?
  - A. Yes, in my opinion.
- Q. Have you ever inquired of the retail chain pharmacies whether or not they have a

Page 218 1 bonus system or ever had a bonus system for 2. their pharmacist that was driven by the number 3 of prescriptions that they filled either per hour or per day? 4 5 No, I have not. If you -- if you learned 6 0. 7 hypothetically that for a significant period of time, these retail chain pharmacies paid out 8 9 bonuses to their pharmacists based upon the 10 number of prescriptions that they filled, would 11 that change your testimony about that 12 comparison? 13 MR. BARNES: Object to form. I 14 don't think it's appropriate to ask a fact 15 witness a hypothetical question. 16 MR. WEINBERGER: Well, you asked 17 him a very broad hypothetical question and I'm entitled to do the same. 18 19 MR. BARNES: For the record, I did 20 not ask a hypothetical question. 21 If you knew there wasn't such a 22 bonus system, would that change your position as to what incentives might exist within the retail 23 24 chain pharmacies to fill prescriptions? MR. BARNES: Same objection. 25

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Page 219
                 Potentially, but I really don't --
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    I don't know.
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                 In Exhibit 17, further into the
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    exhibit I want you to pull out a Giant Eagle
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    inspection -- full inspection report for August
    31, 2020. It starts Bates stamp 2796421. Let
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    me know when you're there.
                 Yes, I'm here.
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           Α.
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                 MR. BARNES: I'm not there yet.
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    Can you tell me how many pages into the exhibit
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    it is?
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                 MR. WEINBERGER: It's -- I think
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    it's the last inspection report, Bob --
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                 MR. BARNES: Hold on.
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                 MR. WEINBERGER: -- under Exhibit
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    17.
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                 THE WITNESS: Is this the one
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    prepared by --
19
                 MR. WEINBERGER: August 31, 2020
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    prepared by Kimberly Hollingshead.
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                 MR. BARNES: I'm there.
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                 Agent DiFrangia, you've got it in
           Ο.
    front of you?
23
24
           Α.
                Yes.
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                 Do you know Agent Hollingshead?
           Q.
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Page 220 1 Yes. She's an inspector with the Α. 2 Board of Pharmacy. So she has specific duties to 3 inspect pharmacies, as you've previously 4 5 described, which is different from being an 6 agent, correct? 7 Α. Yes. 8 And apparently she was using the same software --9 10 MR. APPEL: I'm sorry. Can we take 11 a very brief break? I have to get my child off 12 the bus. 13 MR. WEINBERGER: Oh, sure. 14 THE VIDEOGRAPHER: Off the record 15 at 3:09. 16 (Recess had.) 17 THE VIDEOGRAPHER: Back on the video record at 3:11. 18 19 BY MR. WEINBERGER: 20 Q. We're looking at an inspection 21 report in Exhibit 17, Defendants' Exhibit 17. 22 Again, just by way of background, this is -these are -- this is a report obtained by the 23 24 Defendants per a subpoena that was issued on the 25 Board of Pharmacy. This report was -- this

inspection was apparently completed by Inspector Hollingshead, correct?

A. Yes.

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- Q. Using the same format as you used in your 2018 inspection report that we previously had discussed, right?
  - A. Yes.
- Q. I want you to go to page 9 of this report. If you go to page 8, this is a section under Section 38 regarding OARRS.
  - A. Okay.
- Q. And it has a number of questions about OARRS. And under Section 5 there's a question, "When should a pharmacist request an OARRS report?" And there is an observation, and it appears that this inspector has taken a lot of the language directly from the regulation that we previously looked at, correct?
- A. Well, actually, that language I believe is like -- it's pretty formatted within the inspections, so, you know, the inspection software does change over time. So this one, it's got that pre-formatted information in there.
  - Q. So it populates from the software,

Page 222 1 correct? 2. Α. Yes. 3 So Section 7, under number 5, on when should a pharmacist request an OARRS 4 5 report, says, "If in doubt, run the OARRS report. You don't know what you don't know. 6 It's okay to say no. You might save a life." 7 Did I read that correctly? 8 9 Α. Yes. 10 And so that's a message in this 11 inspector's report to this Giant Eagle that if 12 there's any doubt or any suspicion about a 13 prescription, you need to run an OARRS report 14 and look at the profile and data to determine 15 whether or not to, in fulfilling the 16 corresponding responsibility, to fill or not 17 fill the prescription, correct? MR. BEISELL: Objection to form. 18 19 Α. The data regarding the OARRS Yes. 20 report. 21 Right. Because if you don't, in 22 fulfilling your corresponding responsibility as 23 a pharmacist, it might be dangerous, it might 24 create a danger to the patient or a risk of 2.5 diversion, correct?

Page 223 1 Α. Yes. 2. Ο. And that's what's meant by it's okay 3 to say no, it's okay to not fill the 4 prescription, right? That's what that means, 5 right? 6 Α. Yes. 7 0. And it says you might save a life if you don't fill the prescription, correct? 8 9 Α. Yes, it says that. 10 Now, is this part of the software Ο. 11 that self-populates now, in --12 Α. I -- I'm not sure. 13 Ο. Or it might have just been a 14 statement typed into this report by this 15 inspector? 16 This was a self-populating No. 17 portion that was in -- it was in there at the 18 time because at the time I was conducting more 19 inspections and, you know, we put our points of 20 emphasis in these so that the pharmacist can 21 have them as a reference. 2.2 Ο. So this goes back, Agent DiFrangia, 23 to what we started out with during my 24 cross-examination, and that is that with 25 dangerous drugs, like opioid prescription drugs,

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it's extremely important that the pharmacist perform their corresponding responsibility using the tools that they have or are given to analyze these prescriptions carefully before dispensing them, correct?

MR. BARNES: Object to form.

- A. I think that's correct in terms of OARRS.
- pharmacy chains had dispensing data that contained significant amounts of information that could identify the red flags that we've talked about earlier and could provide that to the pharmacist, at the pharmacist's computer station in the pharmacy store, as they are looking and potentially dispensing opioid prescriptions, that would certainly assist the pharmacist in fulfilling their corresponding responsibility, true?

MR. BARNES: Object to form. Lack of foundation as to what a pharmacist might do.

- O. You can answer.
- A. I'm not sure what the answer is. I don't know. I'm not a pharmacist. It might be best geared toward a pharmacist.

Page 225 1 MR. WEINBERGER: Agent Difrangia, 2. that's all the questions I have at this time. 3 Thank you, sir. MR. BARNES: I have some follow-up 4 5 questions, unless any of the other Defendants want to go first. 6 7 FURTHER EXAMINATION OF WILLIAM DIFRANGIA BY MR. BARNES: 8 9 0. Agent DiFrangia, you were asked some 10 questions about the August 31st, 2020 inspection 11 in Exhibit 17 prepared by Inspector Kim 12 Hollingshead. That was just a couple minutes 13 ago. 14 Α. Yes. 15 Okay. You didn't perform that 16 inspection, you weren't there, and you don't 17 have any personal knowledge of that inspection; is that correct? 18 19 That's correct. Α. 20 But this inspection does result, on Q. 21 the last page, "No issues found by this 22 inspector"; is that correct? 23 Yes, that's correct. Α. 24 Ο. You were asked some questions in 25 this report about paragraph 5, which is related

Page 226 to when to check OARRS. And you and I earlier 1 2. today went through all of that, right, what the 3 regulation actually says? Do you recall that? 4 Α. Yes. 5 And, in fact, this number 38, items 1 through 6, appear to be taken right from that 6 7 regulation; is that right? In the Observation portion? 8 Α. 9 0. Yes. 10 Α. Yes. 11 In fact, that appears to be right Ο. 12 out of Exhibit 10, regulation 4729-5-21, 13 Subsection D, items 1 through 6. You can take a look back at it, but I think it's a direct cut 14 15 and paste out of that regulation, correct? 16 Yeah, it -- it certainly seems that 17 it is. 18 Okay. And the regulation is the Q. actual -- sets forth the actual times when the 19 20 Ohio Board of Pharmacy tells a pharmacist these 21 are the times when we want -- when you have to check OARRS, and it lays out those parameters 22 23 that we went over, correct, items 1 through 6 of 24 Subsection D of the regulation? 25 Α. Yes.

- Q. Okay. Did the Board of Pharmacy at any time ever impose a regulation that said it required the pharmacist to check OARRS each and every time it filled a prescription?
  - A. To my knowledge, they have not.
- Q. Okay. You told me earlier that filling prescriptions involves a lot of professional judgment on behalf of the pharmacist; is that right?
  - A. Yes.

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- Q. So if, in the professional judgment of a pharmacist, he or she felt that he or she wasn't required under the regulation to check OARRS but in their professional judgment wanted to check OARRS, they could do that; is that right?
  - MR. WEINBERGER: Objection.
  - A. Yes.
- Q. Okay. You were asked some questions about that inspection of the Giant Eagle pharmacy that you and I went over. You had told me earlier -- you had said that this was the only full-blown inspection that you had conducted of a Giant Eagle store in Trumbull County; is that right? You testified to that?

Page 228 1 Yes. Α. 2. Ο. And you had told me earlier that you 3 also inspected other Giant Eagle stores in other counties, correct? 4 5 Α. Yes. And did you find in those 6 Ο. 7 inspections across multiple counties that the Giant Eagle stores had a corporate-wide system 8 of software and policies and procedures that you 10 saw repetitively doing the same thing that the 11 other stores were doing? 12 MR. WEINBERGER: Objection. 13 Improper redirect. 14 I'm sorry. What was your answer? Ο. 15 Α. Yes. 16 Okay. There was a reference -- you Ο. 17 made a reference to Giant Eagle's pharmacies are 18 inside the grocery stores. Do you recall that? 19 I -- yeah, I think I do remember Α. 20 making that reference. 21 Okay. Did that mean anything to you 22 as an agent, that the pharmacies were not 23 stand-alone pharmacies on a corner but actually 24 embedded inside grocery stores, with respect to

your inspections? Was that a neutral item, a

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positive item or a negative item?

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- A. It had no influence on my inspections.
- Q. Okay. Now, when you go in for your inspections, the Giant Eagle pharmacist doesn't tell you what you're going to look at; is that correct?

MR. WEINBERGER: Objection.

- A. That's correct.
- Q. In fact, under the regulations that we went over, it's you as the agent are the one telling the pharmacist what you're going to look at and what they're going to provide if they want their license to continue; is that right?

  MR. WEINBERGER: Objection.
  - A. That's correct.
- Q. All right. So when you look at patient profiles, for example -- you were asked some questions on cross about patient profiles -- do you find that the software systems used across these chain pharmacy stores tend to or almost always have the same type of system, so if you see a patient profile in a software system at one Giant Eagle store, you are going to tend to see the patient profile

Page 230 1 system at another Giant Eagle store? 2. MR. WEINBERGER: Objection. 3 Yeah. Pretty much from what I've Α. seen, they're all similar. 4 5 Okay. So the fact that you would 0. 6 look at one patient profile in this December 18, 7 2018 inspection, that number of profiles that you wanted to look at, was that based in part 8 9 upon what you had seen before and your 10 familiarity with the software and how the 11 patient profiles worked in that software? 12 MR. WEINBERGER: Objection. 13 Α. Yes. It was similar to documents and records that I've seen before from Giant 14 15 Eagle. 16 Okay. And if you had wanted to look 0. 17 at any additional patient profiles, you 18 certainly had that right; is that right? 19 MR. WEINBERGER: Objection. 20 Yes. Α. 21 Okay. And if you wanted to check 2.2 how far back dispensing records went, you could 23 have done anything you wanted, checked the 24 software, talked to technicians, looked at the 2.5 records? There was no boundary on what you

Page 231 could do when you were in there in the 1 inspection; is that right? 3 Α. That's correct. Okay. The same with the software 4 0. 5 systems; you had seen software systems in your other inspections of chain pharmacy stores, so 6 7 when you went in to do another inspection, if you saw the same system, oftentimes, am I 8 correct, that it's software you had already seen 10 in other stores? 11 MR. WEINBERGER: Objection. 12 Yes, in regards to retail chain Α. 13 pharmacies. 14 Okav. It was a little bit different 0. with independents. Did they have different 15 16 software systems or no software systems? 17 Yeah, they have, you know, different software vendors from independent 18 19 chain -- or independent pharmacy to independent 20 pharmacy. 21 All right. You were asked some 2.2 questions on cross about insufficient 23 supervision, Section 11 of these reports, and I 24 believe you testified that in the several hours

that you spend in these pharmacies, including

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during busy times, you're able to observe whether or not they appear to be sufficiently staffed; is that right?

MR. WEINBERGER: Objection.

A. Yes, that's correct.

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- Q. All right. And I think you told me earlier that before you even go in for these inspections, as an agent for the Board of Pharmacy, you have full knowledge of every prescription and the volume of prescriptions written by these stores or filled by these stores before you even go in for your inspections, right? I mean, if you wanted to get that information, it was available?
- A. Yeah. If I wanted to, I could get all the controlled substance dispensings from a pharmacy prior to an inspection, and if it was relevant, if there was a relevant investigation to do so.
- Q. All right. And with respect to looking at dispensing records themselves, those were fully available to you as an agent of the board when you went in for your inspections or otherwise? If you wanted to see the entire dispensing data in addition to the OARRS data

you already had, you could demand that and get it during your inspections, correct?

MR. WEINBERGER: Objection.

A. Yes, that's correct.

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- Q. In your inspections you were asked some questions about incentives and there was a reference back to your earlier testimony of independent, family-owned pharmacies having higher incentives, profit incentives to fill prescriptions. My follow-up question is, with respect to the retail pharmacy Defendants, bonus information was available to you at any time, compensation of pharmacists or pharmacy techs; is that correct? If you wanted to see it, you could demand it and you would get it; is that right?
- A. I don't know. I don't know that I've ever asked for it and I don't know if there would be pushback.
- Q. Okay. But it wasn't something that you as a board agent generally looked at as part of your inspections; is that right?
  - A. That's correct.
- Q. And sitting here today, Agent
  DiFrangia, are you aware of any Ohio regulation

Page 234 1 that regulates how pharmacists are compensated 2. one way or the other? 3 No, I'm not aware of anything like Α. 4 that. 5 You were asked a lot of questions 0. early in the cross-examination about whether or 6 7 not your testimony was based upon your experience only as a board agent, and I believe 8 9 you at one point indicated that you also had 10 prior experience that we went over in law 11 enforcement. So am I understanding that the 12 testimony that you've provided today is a 13 combination not only of your board experience 14 but also your prior law enforcement experience? 15 Α. It is. 16 And you've certainly had 17 interactions with the pharmacy Defendants' 18 stores and pharmacists for many years prior to 19 becoming a board agent; is that right? 20 Yes, that's correct. Α. 21 I want to pull up DiFrangia Exhibit You were asked a lot of questions about 2.2 23 that. Are you with me? 24 Which --Α. Yes. 25 Ο. At binder 2 near the end, DiFrangia

Page 235 Exhibit 9. 1 Okay. Yes, Exhibit 9. 2. Α. 3 I had asked you some overview Ο. questions. I want to follow up due to the 4 5 questioning on cross. This document is captioned 6 7 "Prescription Drug Investigation Techniques and Workflow." Is this an indication to you that 8 this is a board internal document related to 10 how the board agents and inspectors -- the 11 suggested way to perform their functions? 12 Yes, but this is more or less 13 tailored for agents, not so much inspectors. 14 Okay. And so do you know if this --0. 15 when or how this was prepared and by whom? 16 I do not know. 17 Okay. The first big section, items Q. 18 1 through 21, Data Anomalies, is this a 19 reference to the OARRS data that is available to 20 the board and its agents when conducting 21 investigations? 2.2 Α. Yes. So, for example, data anomaly number 23 24 1 and 2, large total number of patients and daily patient breakdown, that's something that a 25

Page 236 board agent can go into the OARRS data and look 1 2. at prescribers generally and determine the 3 number of patients and the daily patient breakdown; is that right? 4 5 Yes, just for controlled 6 substances. 7 For controlled substances. 0. But this is not something that a 8 9 pharmacist could do, correct? They couldn't go 10 into the OARRS data and take a look at how 11 many -- the number of patients that a 12 prescriber has or the daily patient breakdown 13 for controlled substances, correct? 14 MR. WEINBERGER: Objection. 15 Q. We covered that earlier? 16 Α. Correct. 17 So when you were asked on cross 18 about whether these were red flags, correct me 19 if I'm wrong but these are internal -- you call 20 them data anomalies that board agents would look 21 at based upon their special access to the OARRS 2.2 data, correct? 23 Α. Correct. 24 And would that include number 3, Ο. 25 large overall volume of prescriptions? Is that

Page 237 special board agent access only; as part of 1 2. doing an investigation of a prescriber, you would be able to go in and look at the total 3 volume of prescriptions issued by a prescriber? 4 5 Yes. Law enforcement also has -would have access to that. 6 7 Okay. And number 4, patients with 0. drug-related criminal histories, that's 8 9 something that is unique to the -- to the board 10 agent, right? I mean, how would a pharmacist, 11 for example, know about a criminal history? 12 That's a law enforcement data point, isn't it? 13 Α. Yes. Okay. So so far, 1 through 4, these 14 0. 15 are internal board agent specific only; am I 16 right? 17 MR. WEINBERGER: Objection. 18 Α. Yes, this is an internal document 19 just for Board of Pharmacy members. 20 Okay. This isn't -- this document Ο. 21 isn't something that was issued to pharmacists 22 and said, you know, look for these things; instead, this is something that is internal to 23 24 the board only, that its agents should consider 25 looking at, correct?

A. Correct.

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- Q. And would that include number 5, prescribing similar drugs in groups, including cocktails? That's a board agent inquiry, not a pharmacist inquiry, correct?
- A. Yes. It's -- like I said, it is issued to board agents and other board staff.
- Q. Okay. So if I went through each one of these items, the remainder, 6 through 21, would you give me the same answer, that each one of these things is internal -- is an internal board agent data point to consider in investigations and not a pharmacist's requirement?
  - A. Yes.
- Q. Okay. And then down below on the General Workflow, is this section of this internal -- board only internal report a general description of how to do your investigation once you consider the data anomalies?
- A. Yeah. This is generally, you know, a work flow of how to -- how to interpret some of the data and come to a conclusion after reviewing it.
  - Q. Are you familiar with the algorithms

and formulas used by the board, the OARRS department, to analyze the prescription data that's coming into the board on a daily basis?

A. No.

- Q. Do you know that they do run algorithms and the formulas to analyze the data, the prescription data, to provide investigative leads to the agents?
- A. I know OARRS provides leads but I don't know how they -- how they get to them.
- Q. Okay. And so DiFrangia Exhibit 9 is, you told me, an internal document. This is not something that's in the regulations that we went over; is that correct?
  - A. Correct.
- Q. So when Mr. Weinberger was asking you questions about red flags, did you -- were your answers to him in the context of these are red flags for the board agents internally?
  - A. Yes.
- Q. Do you know, in your four and a half years and prior experience actually in law enforcement, to your knowledge, were pharmacies or pharmacists ever required to analyze data anomalies as reflected on this Exhibit 9 or was

Page 240 that a board responsibility? 1 2. I don't know if any pharmacist was ever asked to review this. Again, this is all 3 internal board documents. 4 5 Okay. You were asked some questions about the pharmacist's corresponding obligation 6 7 and it being a so-called last line of defense. Do you recall that questioning? 8 9 Α. Yes. 10 But, in your experience, Agent DiFrangia, the first line of defense is the 11 12 doctor, correct? 13 MR. WEINBERGER: Objection. 14 Leading. 15 Α. Yeah, in my opinion and my 16 experience. 17 MR. WEINBERGER: Move to strike. 18 Bob, we can't hear you. 19 THE VIDEOGRAPHER: Off the record 20 at 3:40. 21 (Recess had.) THE VIDEOGRAPHER: We are back on 2.2 the record at 3:43. 23 24 BY MR. BARNES: 2.5 Agent DiFrangia, sorry about that Q.

Page 241 technology break. I don't know if you heard my 1 last two questions. I didn't realize my 2. microphone had died. But we were talking about 3 the doctors being the first line of defense in 4 5 prescribing. Do you recall that? 6 Α. Yes. 7 0. And my follow-up question was, in your experience, it's the doctor that examines 8 9 the patient and diagnoses the patient and treats 10 the patient, correct? 11 Α. Yes. 12 Before issuing the prescription, 0. 13 correct? 14 Α. Yes. 15 0. And when the patient shows up at the 16 pharmacy and presents that prescription, it's --17 in your understanding, it's not the role of the 18 pharmacist to exercise medical judgment or 19 interfere with the medical judgment of the 20 doctors; is that correct? 21 MR. WEINBERGER: Objection. 2.2 Α. That, I'm not sure. 23 All right. Well, we went over the 0. 24 regulations as to what a pharmacist is supposed to do when filling a prescription and I didn't 2.5

Page 242 recall seeing anything like examine the patient 1 2. or diagnose the patient or come up with a treatment plan for the patient. Do you agree 3 with me on that? 4 5 MR. WEINBERGER: Objection. 6 Α. Yes. 7 0. Okay. Are your inspections influenced by past inspections of the same 8 9 pharmacy chain? For example, if you have 10 repetitively good inspections at a pharmacy 11 chain, does that influence the nature and scope 12 of your ensuing inspections? 13 MR. WEINBERGER: Objection. 14 Α. It's just based on the 15 pharmacy that I'm in at that point in time. 16 Okay. Beyond the regulations that 17 we went through, the manner of dispensing 18 prescriptions regulations that we went through 19 this morning, are you aware of any other 20 regulations that required the pharmacies to do 21 anything more beyond those regulations? 2.2 MR. WEINBERGER: Objection. 23 Α. As far as just for manner of 24 issuance of prescriptions? 2.5 Q. Correct.

A. I mean, I think there's some more that -- but I don't -- I can't think of them off the top of my head.

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Q. All right. And certainly if the board wanted the pharmacies or pharmacists to issue prescriptions in a certain way by considering certain data, they would have put it in a regulation; is that correct?

MR. WEINBERGER: Objection.

- A. That, I don't know.
- Q. Are there a lot of reasons why a doctor might have a lot of patients that, in your mind, don't raise any suspicion at all?

  MR. WEINBERGER: Objection.
- A. I'm sorry. Can you -- could you repeat that?
- Q. Yeah. I'm referencing back to that Exhibit 9 that we went over and the number one item was large total number of patients, and I'm just curious, could a doctor have a large number of patients and be totally legit in terms of the way they're practicing?

MR. WEINBERGER: Objection.

A. Yeah. I mean, I think in my opinion I believe they can. If the vast

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Page 244

majority of their patients aren't receiving any type of controlled substances, then we could -- you know, we could potentially assume that it's not any type of pill mill or anything of that nature.

Q. And so is that something that you ever looked at, I'll call it the ratio of controlled substance prescriptions versus overall prescriptions for a pharmacy? Is that a relevant piece of information if you were trying to consider, you know, whether the pharmacy was doing anything inappropriately?

MR. WEINBERGER: Objection.

- O. Does that make sense to you?
- A. It does. I've never looked at it.

  It could be -- always could be useful to look

  at, but I've never looked at that.
- Q. Okay. Can you determine whether a doctor is prescribing inappropriately based upon the volume of prescriptions alone or do you need to do a lot more work before you come to that conclusion?

MR. WEINBERGER: Objection.

A. I would like to do more. I would like to see more things -- me personally, I

Page 245

would like to see additional things that are leading in that direction, not just a large amount of prescriptions.

Q. All right. But it's an internal board agent anomaly that is listed here that is something to consider, correct?

A. Yes.

- Q. But it's merely the starting point, not the ending point, right?
  - A. Yes.

2.

- Q. There's a listing here of age of patient, 18 to 40. Why would the board internally have its agents consider that? What does that have to do with anything?
- A. My guess, the way I interpret this is that, you know, there may be concern if you have a large amount of 20-year-olds obtaining maybe some opiates, for example.
- Q. So that's something internally the board is saying agents should look at?
- A. It's something to be considered with everything else in this.
- Q. But the mere age of a patient doesn't necessarily indicate anything wrong is going on, there's legitimate reasons why

patients in that age group might need an opiate prescription; do you agree with that?

A. Yes.

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- Q. And, generally, Agent DiFrangia, do you agree with me that there are many legitimate medical reasons for prescribing opioids and opioids in combination with other drugs based upon the needs of patients?
- A. You know, again, I don't -obviously I'm not a doctor and I don't know
  what -- you know, I don't know that I can
  answer that.
- Q. Okay. And you do know that opioids dispensed through pharmacies are drugs that have been approved and gone through appropriate review channels, for example, by the FDA, they've been approved for distribution and are legal drugs that the federal authorities have said deserve to be manufactured and dispensed? You know that, correct?
  - A. Yes.

MR. BARNES: I've got nothing further. Thank you, Agent DiFrangia.

24 Anybody else?

Okay. Thank you, sir.

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Page 247
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                 MR. BEISELL: I'm sorry, Bob.
2.
    have a few questions.
3
                 MR. BARNES: Sorry. Go ahead.
                 MS. CONROY: This is Mildred Conroy
4
5
    for the Plaintiffs. I just want to make sure
6
    Pete Weinberger can hear us.
7
                 MR. WEINBERGER: I got kicked off
    for the last three minutes. So, Laura, what
8
9
    were you about to say?
10
                 MS. CONROY: It's Mildred. I was
11
    just -- they were about to stop questioning and
12
    I just wanted to make sure you were there.
13
                 MR. WEINBERGER: I got kicked off
14
    but go ahead and proceed.
15
                MR. BARNES: Any follow-up
16
    questions by Plaintiffs?
17
                 MR. WEINBERGER: I have no further
18
    questions.
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                 MR. BARNES: All right. Because
20
    you got kicked off, Pete, I wanted to make sure
21
    that no other Plaintiffs' counsel has follow-up
22
    questions.
23
            EXAMINATION OF WILLIAM DIFRANGIA
24
    BY MR. BEISELL:
2.5
                Agent DiFrangia, can you hear me all
          Q.
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Page 248 1 right? 2. Α. Yes. 3 Great. I just have a couple of 0. really small questions to clean up some 4 5 testimony from earlier this morning. So you've been an agent with the 6 7 Ohio Board of Pharmacy since November 2016, right? 8 9 Α. Yes. 10 And your area of responsibility from 11 that time period to the present has included 12 Trumbull County but not Lake County. Am I 13 understanding that correctly? 14 That's correct. Α. 15 0. Earlier this morning, and correct me 16 if I'm wrong, you testified that you never 17 personally conducted an inspection of a Walmart pharmacy in Trumbull County; is that correct? 18 19 That's correct. Α. 20 Why is that? Q. 21 Where I inspect pharmacies, sometimes I try to be judicious about it. 22 it's involving an investigation, you know, I'll 23 24 do it in conjunction with that just to really 2.5 manage my time.

- Q. So is it -- would it be fair to say that you didn't feel the need to inspect and conduct a full inspection of the Walmart pharmacies in Trumbull County?
- A. I'm sure there was a time where I felt that -- there just was nothing that was directing my attention there.
- Q. Understood. And you also mentioned collaborating with a Walmart district pharmacy manager relating to diversion. Do you remember that testimony?
  - A. Yes.

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- Q. Do you remember that person's name, by chance?
- 15 A. I don't.
- 16 Q. Okay. I know it's a bit of a test 17 all day long.
- Do you recall the specifics of that particular collaboration with the district manager?
  - A. Yes. He called me regarding -- it was a pharmacy technician that -- she was not diverting drugs. She was stealing merchandise from -- from the Walmart store.
    - Q. But not pharmacy related?

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Page 250
1
           Α.
                Correct.
 2.
                 Understood.
           0.
 3
                 MR. BEISELL: Thank you, Agent
    DiFrangia. I don't have any further questions,
 4
 5
    unless anyone else does.
                 MR. BARNES: Okay. That wraps it
6
7
    up.
8
                 Henry, you going to review the
9
    transcript I suppose?
10
                 MR. APPEL: Yes, Mr. DiFrangia will
11
    review the transcript and sign.
12
                 THE VIDEOGRAPHER: Going off the
13
    record at 3:55.
14
15
           (Deposition concluded at 3:55 p.m.)
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Page 251 Whereupon, counsel was requested to give instruction regarding the witness' review of the transcript pursuant to the Civil Rules. SIGNATURE: Transcript review was requested pursuant to the applicable Rules of Civil Procedure. TRANSCRIPT DELIVERY: Counsel was requested to give instruction regarding delivery date of transcript. 

Page 252 1 REPORTER'S CERTIFICATE 2. The State of Ohio, ) SS: 3 County of Cuyahoga. 4 5 I, Renee L. Pellegrino, a Notary Public 6 7 within and for the State of Ohio, duly commissioned and qualified, do hereby certify 8 that the within named witness, WILLIAM DiFRANGIA, 10 was by me first duly sworn to testify the truth, the 11 whole truth and nothing but the truth in the cause 12 aforesaid; that the testimony then given by the 13 above referenced witness was by me reduced to stenotypy in the presence of said witness; 14 afterwards transcribed, and that the foregoing is a 15 16 true and correct transcription of the testimony so given by the above referenced witness. 17 I do further certify that this 18 19 deposition was taken at the time and place in the 20 foregoing caption specified and was completed 21 without adjournment. 2.2 23 2.4 2.5

Page 253 I do further certify that I am not a relative, counsel or attorney for either party, or otherwise interested in the event of this action. IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, on this 19th day of January, 2021. Leve L. Pellegrino Renee L. Pellegrino, Notary Public within and for the State of Ohio My commission expires October 12, 2025. 2.2 

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      January 19, 2021
5
      To: MR. APPEL
 6
      Case Name: National Prescription Opiate Litigation - Track 3 v.
7
      Veritext Reference Number: 4399733
8
      Witness: William DiFrangia Deposition Date: 1/14/2021
9
10
      Dear Sir/Madam:
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      Enclosed please find a deposition transcript. Please have the witness
12
      review the transcript and note any changes or corrections on the
13
      included errata sheet, indicating the page, line number, change, and
14
      the reason for the change. Have the witness' signature notarized and
15
      forward the completed page(s) back to us at the Production address
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      above, or email to production-midwest@veritext.com.
17
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      If the errata is not returned within thirty days of your receipt of
19
      this letter, the reading and signing will be deemed waived.
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		Page 255
	DEPOSITION REV	IEW
	CERTIFICATION OF	WITNESS
2		
	ASSIGNMENT REFERENCE NO: 4399	733
3	CASE NAME: National Prescript	ion Opiate Litigation - Track 3
	DATE OF DEPOSITION: 1/14/2021	
ł	WITNESS' NAME: William DiFran	
5	In accordance with the	
	Procedure, I have read the en	_
	my testimony or it has been r	
7	I have made no changes	<del>-</del>
3	as transcribed by the court r	eporter.
	Date Wi	 lliam DiFrangia
	Sworn to and subscribed	
	Notary Public in and for the	•
	the referenced witness did pe	<del>-</del>
	and acknowledge that:	isonally appear
	and definewreage ender	
	They have read the tran	script;
	They signed the foregoi	_
	Statement; and	
	Their execution of this	Statement is of
	their free act and deed	
	I have affixed my name	and official seal
	this day of	, 20
	Notary Public	
	Commission Expira	tion Date

	Page 256	
DEPOSITION REVIEW		
CERTIFICATION OF WITNESS		
ASSIGNMENT REFERENCE NO: 4399733		
CASE NAME: National Prescription Opiate Litigation	- Track 3	
DATE OF DEPOSITION: 1/14/2021		
WITNESS' NAME: William DiFrangia		
In accordance with the Rules of Civil		
Procedure, I have read the entire transcript of		
my testimony or it has been read to me.		
I have listed my changes on the attached		
Errata Sheet, listing page and line numbers as		
well as the reason(s) for the change(s).		
I request that these changes be entered		
as part of the record of my testimony.		
I have executed the Errata Sheet, as well		
as this Certificate, and request and authorize		
that both be appended to the transcript of my		
testimony and be incorporated therein.		
Date William DiFrangia		
Sworn to and subscribed before me, a		
Notary Public in and for the State and County,		
the referenced witness did personally appear		
and acknowledge that:		
They have read the transcript;		
They have listed all of their corrections		
in the appended Errata Sheet;		
They signed the foregoing Sworn		
Statement; and		
Their execution of this Statement is of		
their free act and deed.		
I have affixed my name and official seal		
this, day of, 20		
Notary Public		
Commission Expiration Date		

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	Page 257
1	ERRATA SHEET
	VERITEXT LEGAL SOLUTIONS MIDWEST
2	ASSIGNMENT NO: 4399733
3	PAGE/LINE(S) / CHANGE /REASON
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25	Commission Expiration Date

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# Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES

ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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